

case 402 and top case 404 are a battery pack 410 and an electronic control module 412. A battery cover 416 holds the battery pack 410 in place. In some embodiments, the battery pack 410 may supply a voltage of 18 Volts DC, but systems utilizing other voltages are possible. A user interface 414 enables operation of the saline pump drive unit. A vacuum bottle sleeve 418 may be used when a vacuum bottle is incorporated as the vacuum source 22. A spike 420 is connectable to a fluid source 20, and fluid injectate passes from the fluid source 20 through extension tubing 422 to a disposable piston pump head 500. Saline may be primed through the system by an automatic priming (“self-priming”) system described herein in relation to prior embodiments, or may be primed by gravity from a saline bag that is located (for example on an IV pole) above the rest of the system. A valve on the lowest portion of the system may be opened in order to prime the entire system.

[0066] As illustrated in FIG. 25, the disposable piston pump head 500 is configured to couple to a motor shaft 504 of a motor 502, that is powered by the battery pack 410 of the saline pump drive unit 400. A motor plate 506 and a main body 508 of the disposable piston pump head 500 are secured to each other with screws 510, and hold the internal components of the disposable piston pump head 500. First and second follower plates 512, 514 are held together with screws 516 and bosses 518 extending from the first follower plate 512. The first and second follower plates 512, 514 rotatably hold a cam 520. The cam may be asymmetric (as illustrated) or alternatively may be symmetric. The asymmetry may be incorporated in order to control the amount of noise in the pump, the contours serving to customize the shape of the pressure wave, and of the function of the pump. First and second bushings 522, 524 are rotatably held on first and second pins 526, 528. The pins 526, 528 insert into cylindrical cavities 530, 532 in each of the follower plates 512, 514.

[0067] In use, a user attaches the disposable piston pump head 500 to the motor 502 of the saline pump drive unit 400 by bringing the motor plate 506 close to the motor shaft 504 so that a d-shaped hole 534 in the cam 520 can be pressed over the d-shaped motor shaft 504. Alternatively, the d-shapes may be other non-circular shapes, including, but not limited to elliptical, oval, or rectangular. In operation the motor 502 turns the motor shaft 504, which in turn turns the cam 520. The cam 520 turns, forcing the bushings 522, 524 to push the first and second follower plates 512, 514 back and forth in

a first direction 536 and a second direction 538. A saddle 544 is carried on the second follower plate 514, and a piston 210 may be coupled to the saddle 544 in the same manner as described herein with other embodiments. A supply cylinder 552 and an injection cylinder 554 in the main body 508 are analogous to the supply cylinder 252 and injection cylinder 254 of the cassette 116 of the system 100. The piston 210 of the cassette 116 may be used in the disposable piston pump head 500. The labelled components related to the piston 210 in FIG. 25 are similar to those described in relation to the piston 210 in FIGS. 15 and 16. The outer diameter of the cam 520 may be sized and/or shaped to control the stroke length of the piston 210 and the amount of pulsatility (i.e., the difference between the high and low pressure). In some cases, decreasing the stroke length decreases the amount of pulsatility. In applications within the heart, such as coronary artery applications, lowering the amount of pulsatility can reduce the incidence of bradycardia. To compensate for a lower stroke length, and to maintain a sufficient total flow rate, the speed of the rotation of the cam (i.e. rotations per minute), can be increased, for example by increasing motor output speed, either by gearing or by increased applied voltage. A vacuum spike 546 is used for coupling to the vacuum source 22, for example a vacuum bottle held within the vacuum bottle sleeve 418. A vacuum switch valve 540, which is activated against the bias of a spring 542, may be used to allow pump activation. For example, the electronic control module 412 may be configured to initiate the operation of the motor 502 automatically when the vacuum switch valve 540 sends a signal corresponding to movement of the vacuum switch valve 540, which occurs when a significant vacuum is achieved. This control may be instead of or in addition to control from a vacuum pressure transducer, such as pressure transducer 106. The turning on of the vacuum may thus be used to simultaneously turn on the motor 502, so that a single input begins the operation of the saline pump drive unit 400. Additionally, a vacuum source 22 may be controlled by the electronic control module 412 (for example, by opening or closing a solenoid), when a minimum injectate pressure is measured by an additional pressure transducer. For example, when a pressure of about 0.62 megapascal (90 pounds per square inch) or greater is measured, the vacuum may be activated or communicated to the system. An advantage of the saline pump drive unit 400 is that the user is required only to assemble a single component onto the shaft 504 of the motor 502.

[0068] As previously described, the systems according to any of the embodiments of the present invention may be configured such that active flow of saline

(or other) injectate is not possible without concurrent vacuum being applied for aspiration. Also, the systems may be configured such aspiration is not possible without saline (or other) injectate flow. The systems according to any of the embodiments of the present invention may be configured such that current driving the pump (for example the current driving the motor 302, 502) is monitored, or by any alternative monitoring method, such that when a change in condition occurs, for example, air in the injection system, or clogs in any of the catheter lumens or extension tubes, or leaks within the system, the system shuts down, in order to avoid events such as injection of air into the blood vessels, or catheter or system failure.

[0069] FIG. 26 illustrates an aspiration catheter 700 inserted within a blood vessel 165. The aspiration catheter 700 includes a guidewire lumen 702 secured to the distal end 704 of the aspiration catheter 700 which allows the aspiration catheter 700 to be tracked over a guidewire 706. A supply lumen 708 is secured within an aspiration lumen 710. The supply lumen 708 extends through a tapering tube 712. In some embodiments, the tapering tube 712 may be constructed of polyimide. In some embodiments, the tapering tube 712 may have a luminal inner diameter that tapers from its proximal end to its distal end. For example, in some embodiments, the luminal inner diameter may taper from about 0.3937 mm (0.0155 inches) to about 0.2794 mm (0.011 inches). The supply lumen 708 extends generally parallel to the aspiration lumen 710, however a distal end 714 of the tapering tube 712 curves towards an interior wall surface 716 of the aspiration lumen 710, thus allowing an open end 718 of the supply lumen 708 to act as an orifice for applying a spray pattern 720. The open end 718 of the supply lumen 708 may further promote a jet or spray effect by having an internal diameter that is less than about 0.203 mm (0.008 inches). In some embodiments, the open end 718 of the supply lumen 708 may have an internal diameter that is between about 0.076 mm (0.003 inches) and about 0.102 mm (0.004 inches). The center of the open end 718 orifice may in some embodiments be about 0.3302 mm (0.013 inches) to about 0.4826 mm (0.019 inches) proximal to the most proximal portion 724 of the open distal end 722 of the aspiration lumen 710, as illustrated by distance D in FIG. 26. The most distal portion 726 of the open distal end 722 of the aspiration lumen 710 is slightly distal of the most proximal portion 724 in the embodiment illustrated, and thus has an angled skive, but the skive angle A_s is not severe. A skive angle A_s of between about 75° and about 89°, or between about 80° and about 85° may be used, in order to allow a large portion of

thrombus being pulled into the open distal end 722 of the aspiration lumen 710 to be struck by high velocity exiting jet (e.g. saline) flow, as illustrated with the spray pattern 720.

[0070] FIG. 27 illustrates the catheter 700 of FIG. 26 being utilized to deliver a drug 730 to a target site 732 within a blood vessel 165. The target site 732 may include an atherosclerotic lesion 728 and/or a thrombus 734. Whereas the aspiration of thrombus, as in FIG. 26, involves actively applying a vacuum (e.g., from a vacuum source) on the aspiration lumen 710, the drug delivery illustrated in FIG. 27, though utilizing the same catheter 700, allows the metering of a fine, precision volume flow rate of drug 730 to be delivered into the vessel. This is achieved by having significantly less vacuum applied to the aspiration lumen 710, or no vacuum applied to the aspiration lumen. The precision metering in small, controlled volumes, provides efficient use of typically expensive drugs, with minimal wasted drug. In some embodiments, the drug 730 may be delivered at body temperature. In other embodiments, the drug 730 may be warmed, and delivered at an elevated temperature, for example, to increase the activity and effectiveness of a drug. This may be done, for example, to get a more effective dose, with a smaller volume of drug. In other embodiments, the drug 730 may be cooled and delivered at a reduced temperature (i.e., in relation to the body temperature). The drug 730 may be cooled to control the activity level, or to delay the activity of the drug (e.g., so that it is active downstream, at a location that is not reachable by the catheter 700). In some cases, the drug 730 may be cooled in order to apply a conjunctive therapeutic cooling effect on the tissue being treated. In some cases, the therapeutic cooling effect may be achieved from cooled saline or other aqueous non-drug media alone.

[0071] Some of the drugs 730 which may be delivered include thrombolytic agents (clot busting drugs), such as streptokinase, tissue plasminogen activator (t-PA), recombinant or genetically-engineered tissue plasminogen activator, tenecteplase (TNK), urokinase, staphylokinase, and reteplase. Alternatively, stem cells or “cocktails” containing stem cells may be delivered. In some cases, glycoprotein inhibitors (GPI’s) may be injected through the supply lumen 708 of the aspiration catheter 700. Saline or other aqueous solutions may be delivered alone for selective dilution of blood at the target site 732. In some applications, a solution may be used which is capable of exhibiting a phase change, for example, when its pressure or temperature is changed. In these

applications, a liquid may be injected that becomes a gas when exiting from a small orifice, for example at the open end 718 of the supply lumen 708. Alternatively, a gas may be injected that becomes a liquid when being force through a small orifice, such as the open end 718 of the supply lumen 708. In any of the applications in which drugs 730 or other materials are injected intravascularly through the catheter 700, the injection of the drugs 730 or other materials may occur before, during, after, or instead of an aspiration procedure. Returning to the aspiration catheter 818 of FIGS 21-22, if, during an aspiration procedure, it is desired to deliver drugs down the supply lumen and into the vessel, the tubing set 803 may be removed from the aspiration catheter 818 by disconnecting the male luer 854 of the tubing set 803 from the female luer 851 of the aspiration catheter 818, and the drug may be injected directly into the supply lumen at the female luer 851, for example, by a syringe or metering system, including a syringe/syringe pump combination. By also removing the vacuum source from the female luer 855 of the aspiration catheter 818, when aspiration lumen now serves as an overflow, so that the fluid being delivered into the patient (e.g., intravascularly) is maintained at a controlled rate. The volume of the supply lumen is relatively very small, so only a small volume of drug is needed to fill the supply lumen, and thus reach the distal top of the aspiration catheter 818. This, at the end of the procedure, very little drug is wasted, or needs to be disposed, allowing for a very cost-effective procedure.

[0072] In the embodiments described herein, a sterile fluid path is provided extending all the way from the fluid source 20 to the distal opening 40/open distal end 158 of the catheter 16, 118. In both the embodiments of the system 100 of FIGS. 4-17, the system 800 of FIGs. 21-23, and the embodiments of FIGS. 24-25, a disposable catheter and disposable pump set are configured to be supplied sterile, and coupled to a non-sterile (reusable) pump base 200 or pump motor 502. These combinations allow for reusability of the more expensive components, and for reusability (and maximized sterility) of the less expensive components, thus maximizing cost containment and patient safety at the same time.

[0073] In some cases, parts or all of the devices described herein may be doped with, made of, coated with, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. Some

examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. One or more hydrophilic or hydrophobic lubricious coatings may be used in order to improve trackability of the aspiration catheter 118 through the blood vessels.

[0074] In some instances, a degree of MRI compatibility may be imparted into parts of the devices described herein. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make various portions of the devices described herein from materials that do not substantially distort MRI images or cause substantial artifacts (gaps in the images). Some ferromagnetic materials, for example, may not be suitable as they may create artifacts in an MRI image. In some cases, the devices described herein may include materials that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

[0075] In some instances, some of the devices described herein may include a coating such as a lubricious coating or a hydrophilic coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl celluloses, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

[0076] In one embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the

supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C, such that the spray is at an angle of between about 20° in each direction of the vertical midline of the aspiration lumen.

[0077] In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C; a disposable cassette having a supply cylinder, an injection cylinder and a piston, the disposable cassette configured to releasably couple to at least a motor of the piston pump, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter.

[0078] In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston

pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern impinges on an interior wall of the aspiration lumen when a distal end of the aspiration catheter is immersed within an environment having a temperature of between about 36°C and 38°C; wherein the piston pump includes a supply cylinder, an injection cylinder and a piston, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter; wherein the piston is configured to engage with a saddle associated with the piston pump, the saddle configured for cyclic linear motion, wherein motion of the saddle in a first direction actuates the piston out of the supply cylinder and motion of the saddle in a second direction actuates the piston into the supply cylinder.

[0079] In another embodiment of the present invention, a system for aspirating thrombus includes an aspiration catheter having a high pressure supply lumen and an aspiration lumen, the supply lumen having a proximal end configured to attach to a piston pump and a closed distal end, the aspiration lumen having a proximal end configured to attach to a vacuum source and an open distal end; a first orifice in a side wall of the supply lumen which communicates directly with the interior of the aspiration lumen, the first orifice located proximal to the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen; the piston pump configured to generate a cyclic pressure cycle when attached to the supply lumen, wherein the first orifice creates a spray pattern at least in conjunction with a peak of the piston pump pressure cycle such that the spray pattern includes a jet; wherein the piston pump includes a supply cylinder, an injection cylinder and a piston, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, causing the injection cylinder to increase its

volume of a liquid injectate, the piston further configured to actuate into the injection cylinder while actuating out of the supply cylinder, causing the injection cylinder to decrease its volume by injecting the liquid injectate, and causing the liquid injectate to travel through the supply lumen of the aspiration catheter; wherein a usable volume ratio R_U between the supply cylinder and the invention cylinder is between about 1.15 and about 2.00. Additionally, the usable volume ratio R_U may be between about 1.25 and about 1.85. Additionally, the usable volume ratio R_U may be about 1.40.

[0080] In another embodiment of the present invention a method for delivery of a drug includes providing a catheter including a supply lumen and an aspiration lumen, the supply lumen having a distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end, an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment, providing a disposable tubing set having a first conduit configured to couple the supply lumen of the catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the catheter, and through the orifice into the aspiration lumen, coupling the supply lumen of the catheter to a fluid source, wherein the fluid source contains at least a first drug for intravascular delivery, inserting the catheter within a blood vessel of a patient and advancing the catheter to a target site, coupling the pump component to a drive unit, and operating the drive unit to cause the pump component to inject at least some of the first drug in the region of the target site.

[0081] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The scope of the invention is, of course, defined in the language in which the appended claims are expressed.

[0082] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. The invention, therefore, should not be limited, except to the following claims, and their equivalents. Embodiments of the present invention are contemplated to have utility in a variety of blood vessels, including but not limited to coronary arteries, carotid arteries, intracranial/cerebral arteries, inferior and superior vena cavae and other veins (for example, in cases of deep venous thrombosis), peripheral arteries, shunts, grafts, vascular defects, and chambers of the heart. This includes, but is not limited to, any vessel having a diameter of about two mm or greater. An aspiration catheter 118 outer diameter of about seven French or less is contemplated for many of the applications, though in certain applications, it may be larger. In some embodiments, an aspiration catheter 118 diameter of about six French or less is contemplated. Embodiments of the present invention may even be used in non-vascular applications, for example body lumens or cavities having material accumulations that need to be macerated and/or removed.

[0083] It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they

can also include any third-party instruction of those actions, either expressly or by implication.

WHAT IS CLAIMED IS:

1. A system for aspirating thrombus comprising:
an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a wall and a closed distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end;
an orifice in the wall of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen and adjacent the closed distal end of the supply lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment; and
a tubing set having a first conduit configured to couple to the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.
2. The system of claim 1, wherein the aqueous environment has a temperature of between about 36°C and 38°C.
3. The system of claim 1, wherein the pump component comprises a piston.
4. The system of claim 3, wherein the piston is slidably contained within a supply cylinder and an injection cylinder, the piston configured to actuate into the supply cylinder while actuating out of the injection cylinder, thus causing the injection cylinder to increase its volume of fluid supplied from the fluid source, and wherein the piston is further configured to actuate into the injection cylinder while actuating out of the supply cylinder, thus causing the injection cylinder to decrease its volume by injecting fluid supplied from the fluid source into the supply lumen of the aspiration catheter.
5. The system of claim 4, wherein the piston includes an inner bore having a one-way valve.
6. The system of claim 1, wherein the spray pattern is defined by an angle of between about 1° to about 45° in each direction of the vertical midline of the aspiration lumen.

7. The system of claim 6, wherein the spray pattern is defined by an angle of between about 20° to about 35° in each direction of the vertical midline of the aspiration lumen.

8. The system of claim 1, wherein a usable volume ratio R_U between the supply cylinder and the injection cylinder is between about 1.15 and about 2.00.

9. The system of claim 8, wherein the usable volume ratio R_U between the supply cylinder and the injection cylinder is between about 1.25 and about 1.85.

10. The system of claim 1, wherein the open distal end of the aspiration lumen has a most distal portion and a most proximal portion, and wherein an axial center of the orifice is about 0.3302 mm to about 0.4826 mm proximal to the most proximal portion of the open distal end of the aspiration lumen.

11. The system of claim 1, further comprising a vacuum-activated interface configured to cause the drive unit to start to operate or to remain in an operating condition when a vacuum pressure at the vacuum-activated interface is less than a threshold value, and configured to cause the drive unit to stop or to remain in a non-operating condition when the vacuum pressure at the vacuum-activated interface is greater than the threshold value.

12. The system of claim 11, wherein the vacuum-activated interface comprises a vacuum switch valve.

13. The system of claim 11, wherein the vacuum-activated interface comprises a pressure transducer.

14. The system of claim 1, wherein the open distal end of the aspiration lumen is angled in relation to the longitudinal axis of the aspiration lumen.

15. A system for aspirating thrombus comprising:
an aspiration catheter having a supply lumen and an aspiration lumen, the supply lumen having a distal end, the aspiration lumen configured to couple to a vacuum source and having an interior wall surface, and an open distal end;
an orifice at or near the distal end of the supply lumen, in fluid communication with the interior of the aspiration lumen, the orifice located proximally of the open distal end of the aspiration lumen, wherein the orifice is configured to create a spray pattern when pressurized fluid is pumped through the supply lumen such that the spray pattern impinges on the interior wall surface of the aspiration lumen when a distal end of the aspiration catheter is immersed within an aqueous environment; and

a tubing set having a first conduit configured to couple the supply lumen of the aspiration catheter to a fluid source, and a pump component associated with the first conduit and configured to detachably couple to a drive unit, such that motion from the drive unit is transferred to the pump component such that resultant motion of the pump component causes fluid from the fluid source to be injected through the supply lumen of the aspiration catheter, and through the orifice into the aspiration lumen.

16. The system of claim 15, wherein the supply lumen of the aspiration catheter extends generally parallel to the aspiration lumen, and wherein the distal end of the supply lumen curves towards the interior wall surface of the aspiration lumen.

17. The system of claim 16, wherein the distal end of the supply lumen has an internal diameter that is less than about 0.203 mm.

18. The system of claim 17, wherein the distal end of the supply lumen has an internal diameter that is between about 0.076 mm and about 0.102 mm.

19. The system of claim 16, wherein the open distal end of the aspiration lumen has a most distal portion and a most proximal portion, and wherein an axial center of the orifice is about 0.3302 mm to about 0.4826 mm proximal to the most proximal portion of the open distal end of the aspiration lumen.

20. The system of claim 16, wherein the aqueous environment has a temperature of between about 36°C and 38°C.

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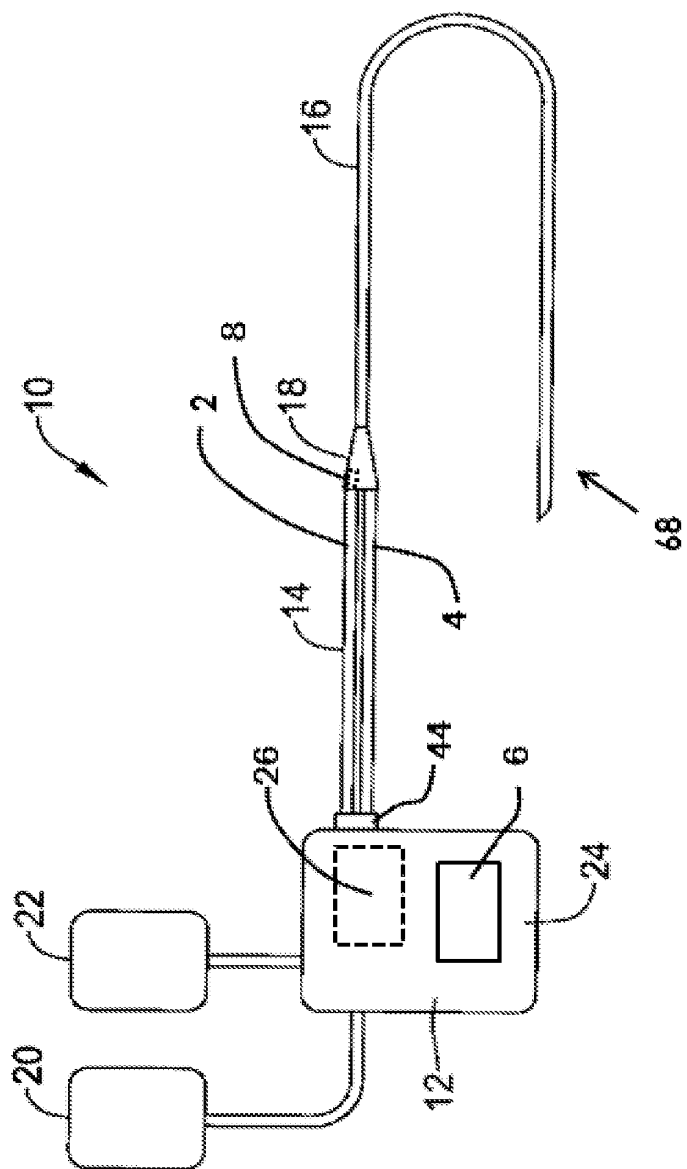


FIG. 1

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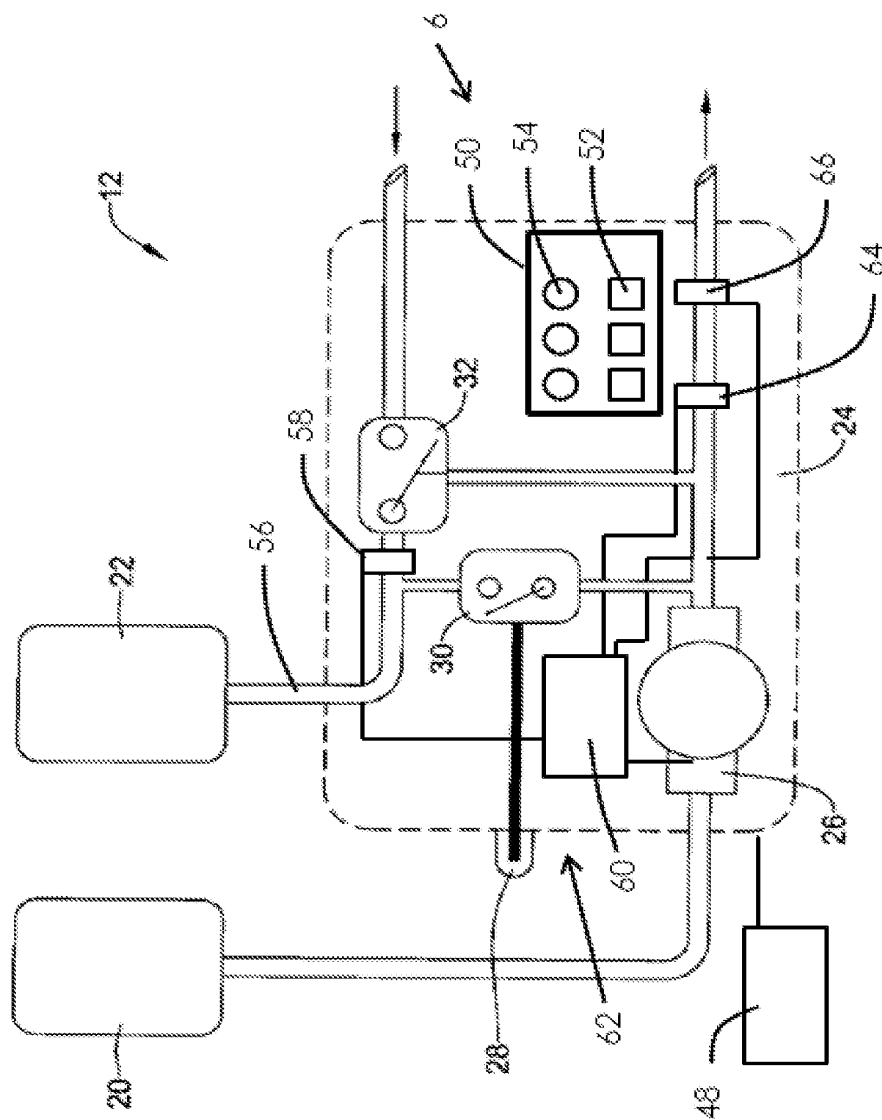


FIG. 2

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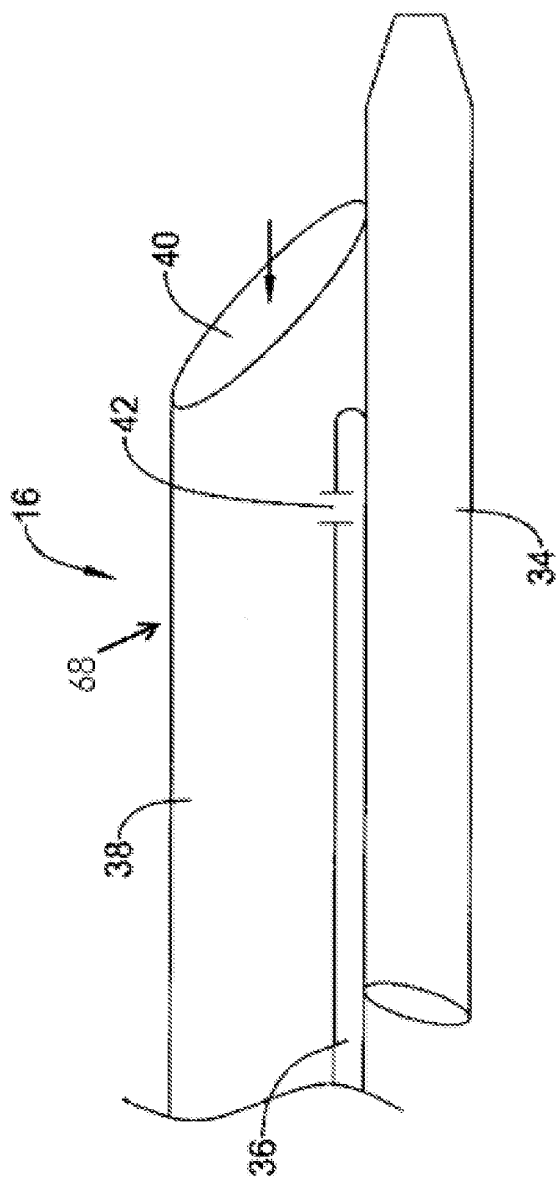


FIG. 3

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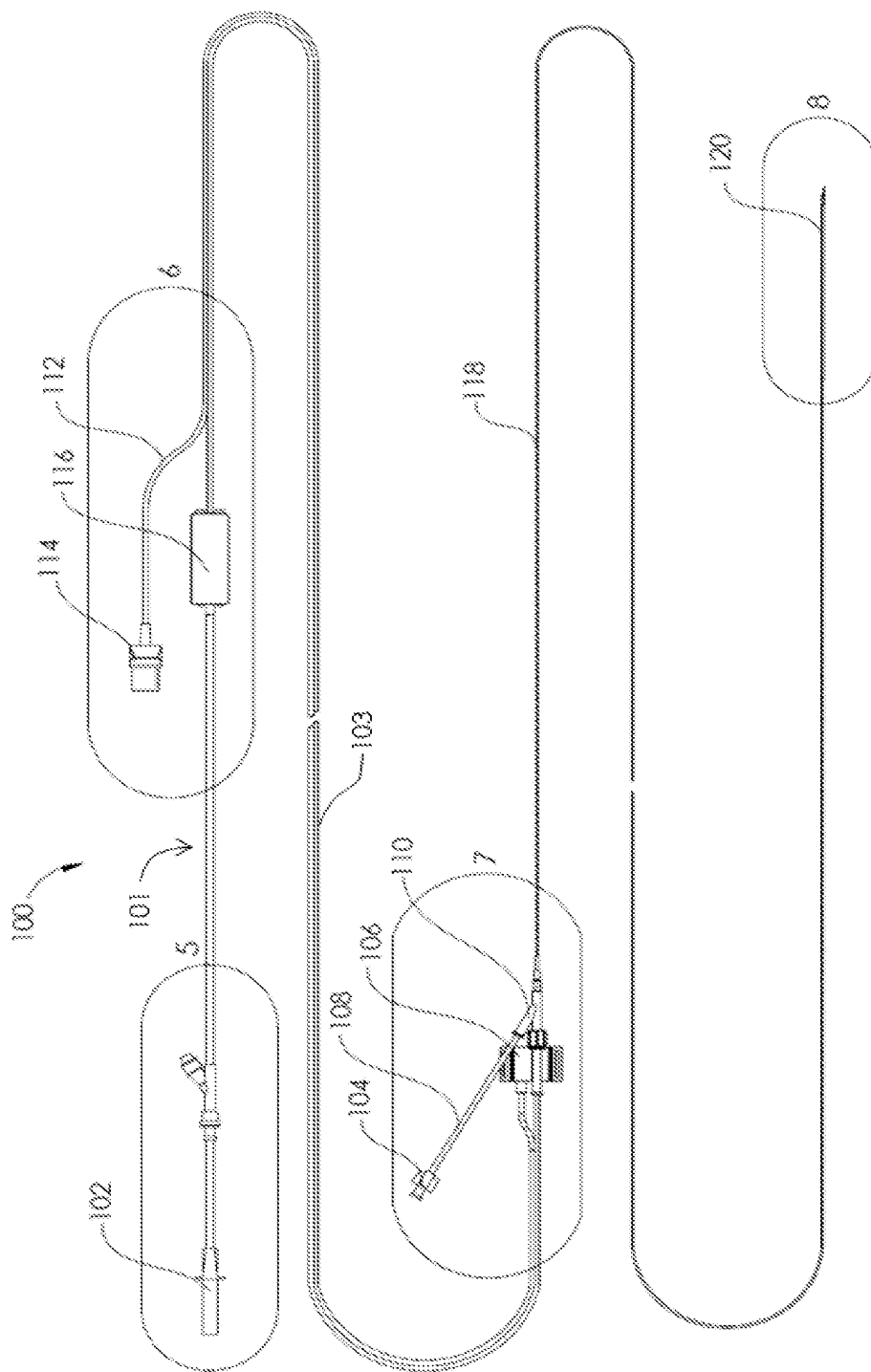


FIG. 4

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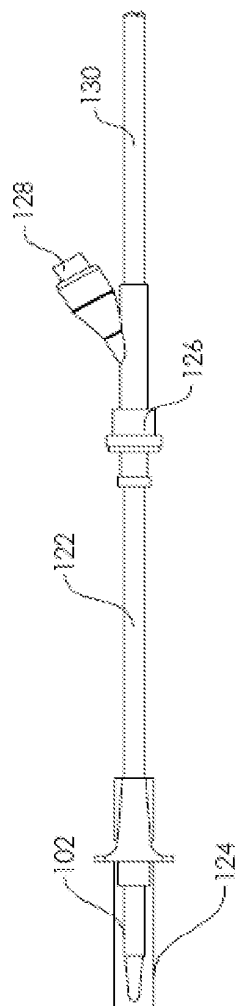


FIG. 5

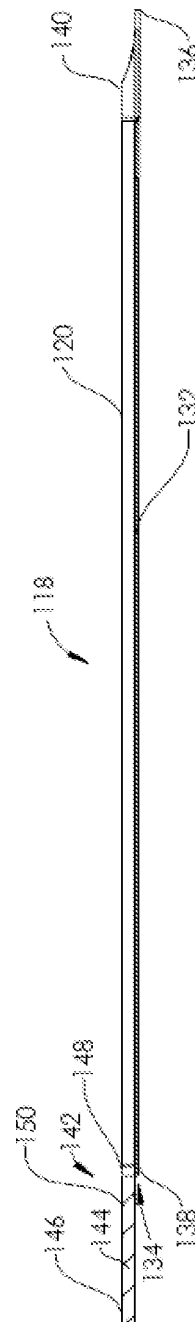


FIG. 8

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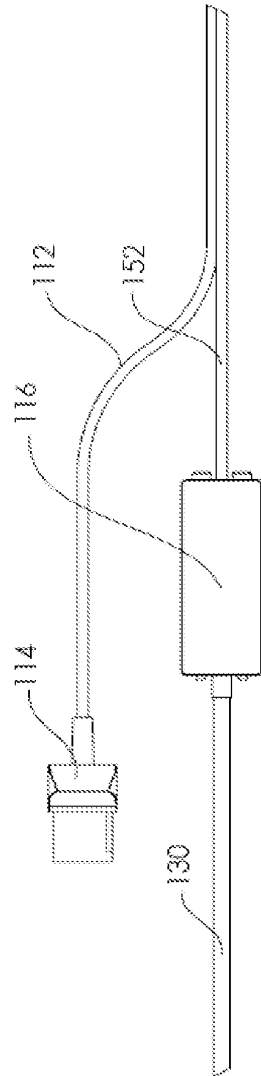


FIG. 6

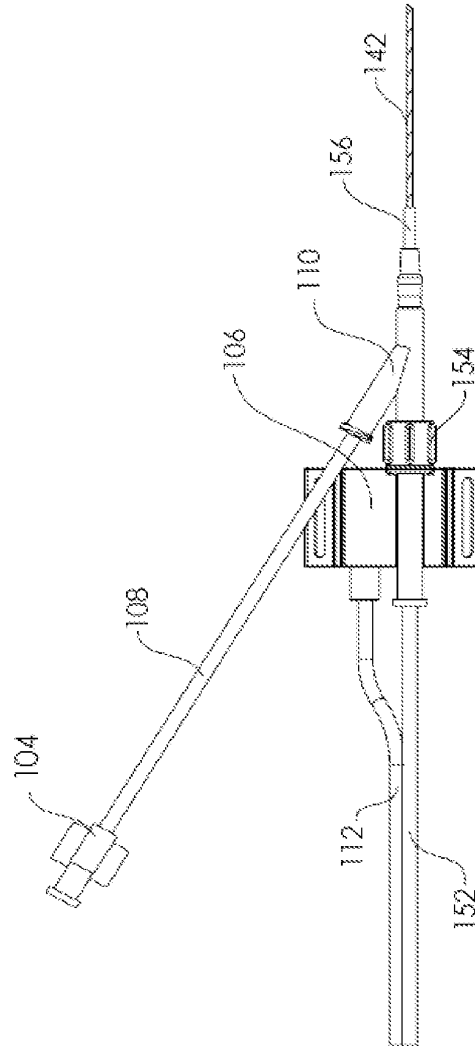
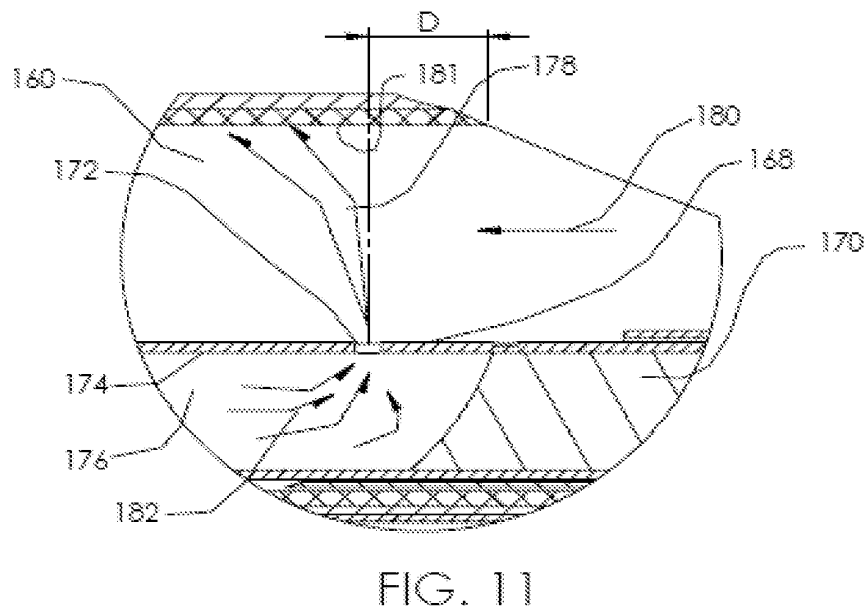
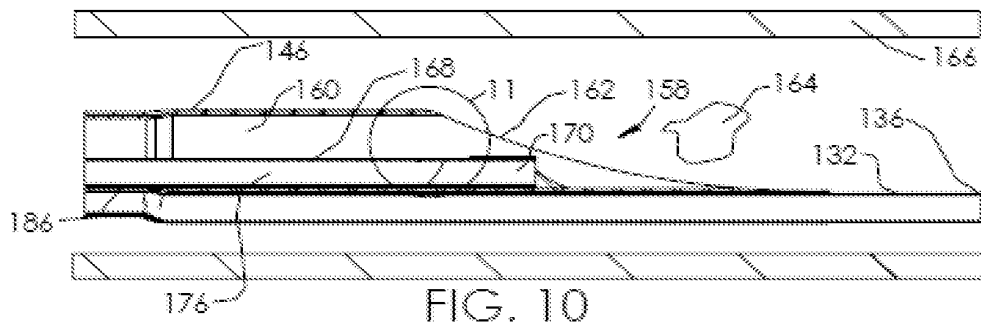
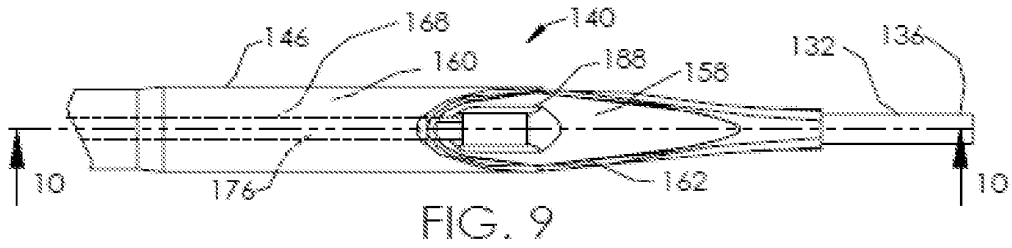


FIG. 7

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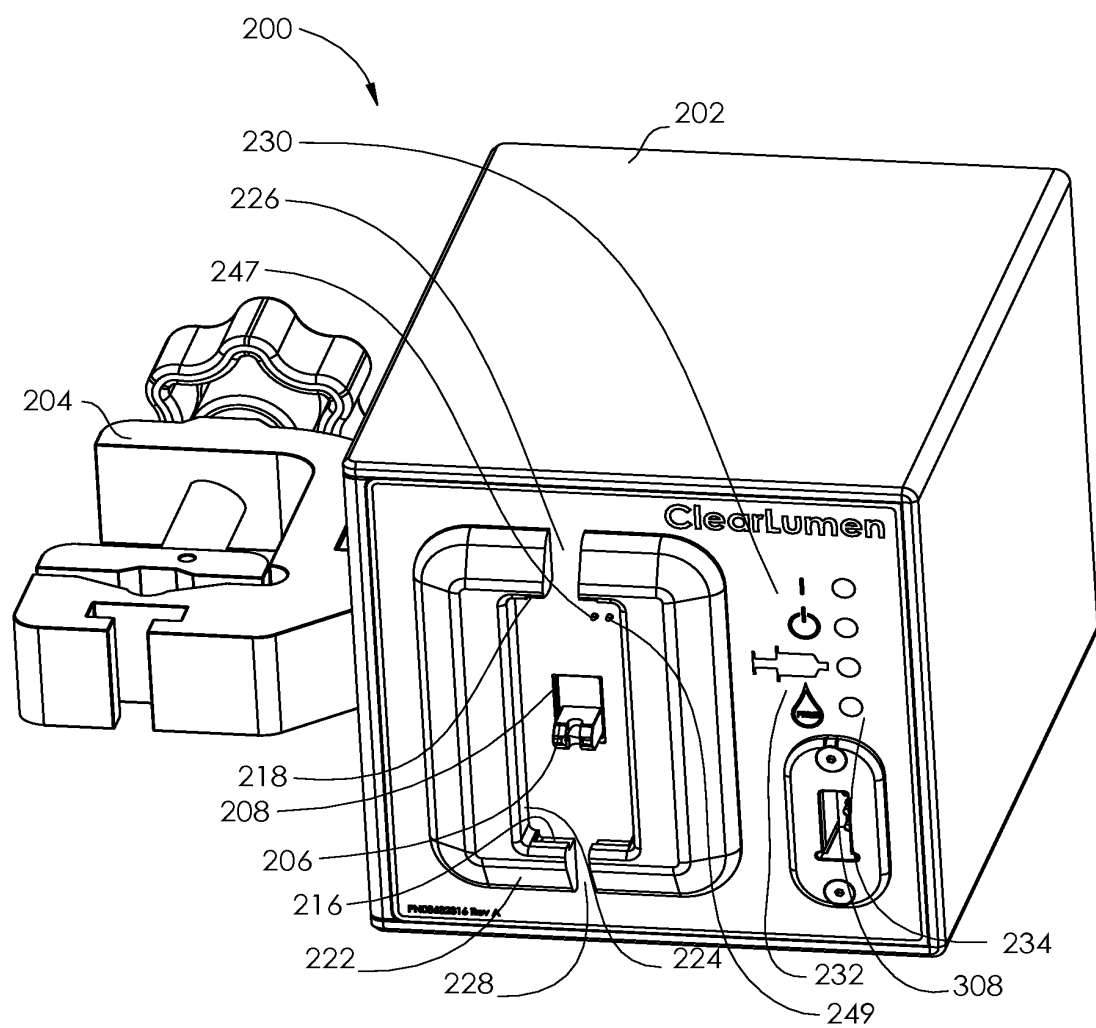


FIG. 12

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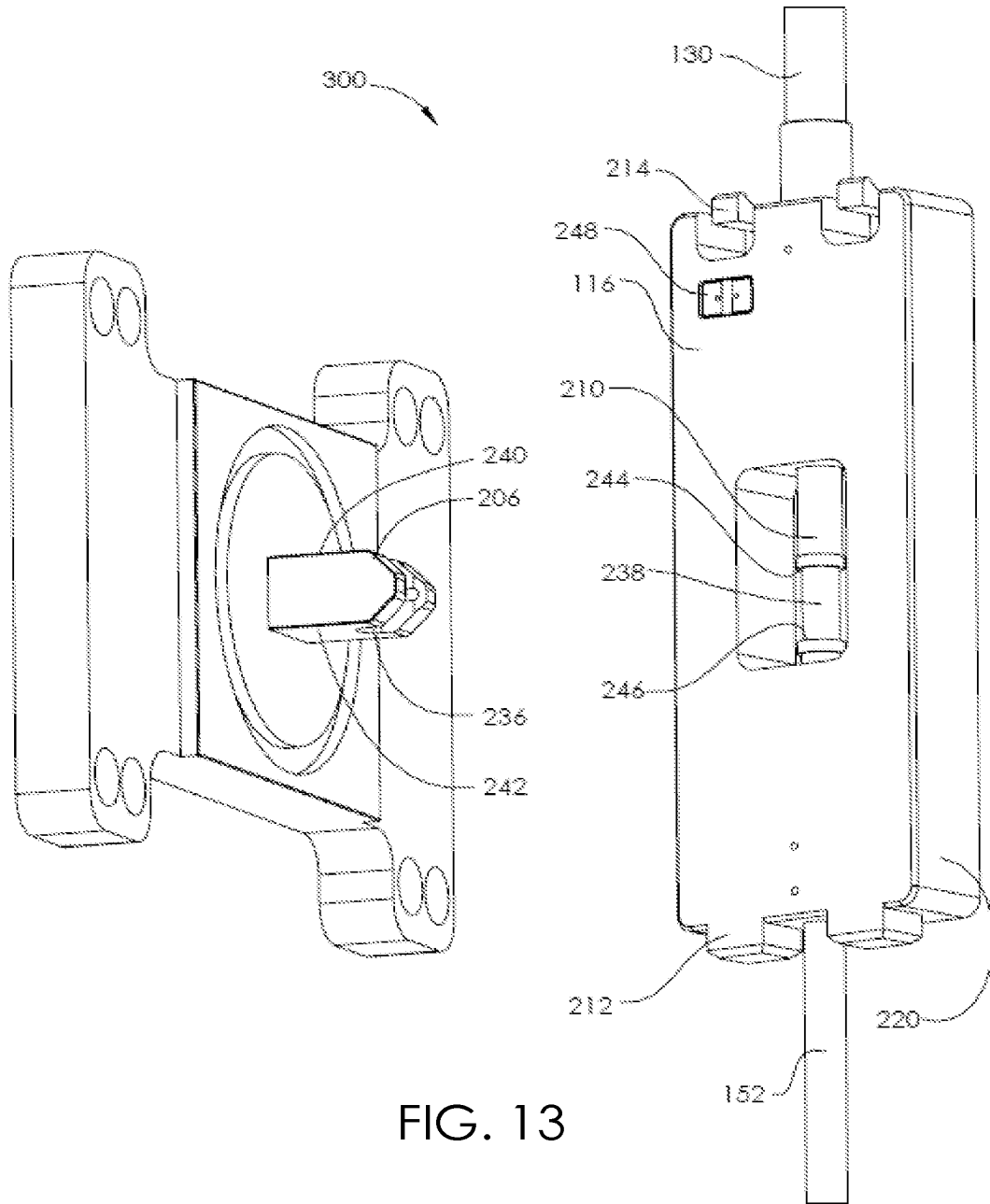


FIG. 13

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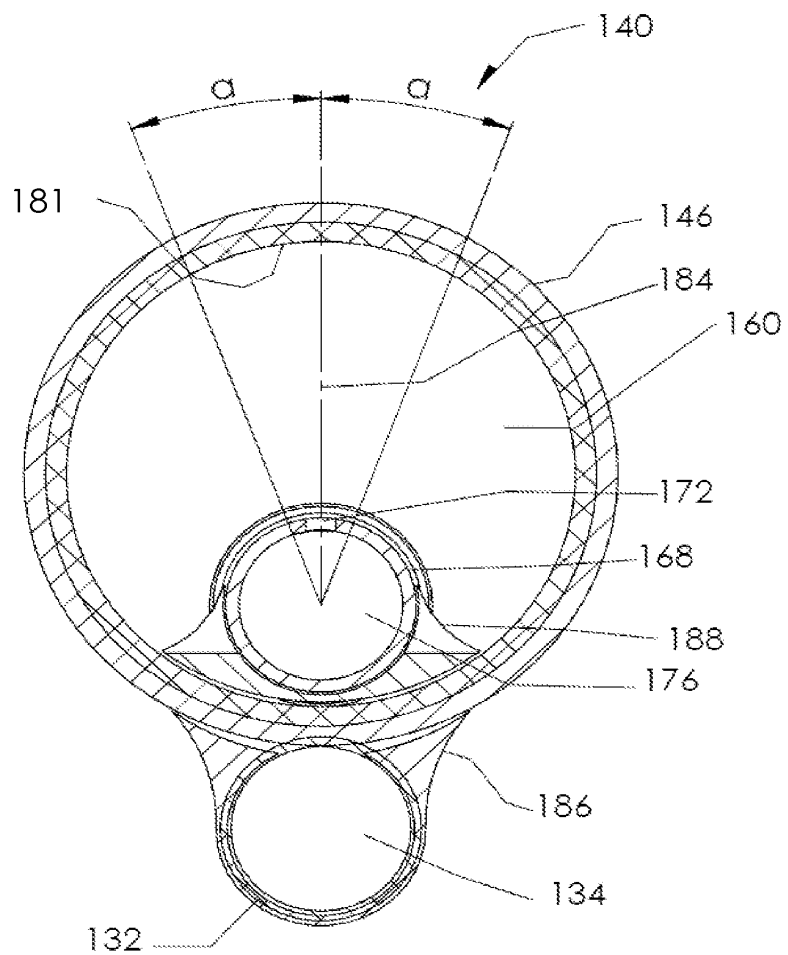


FIG. 14

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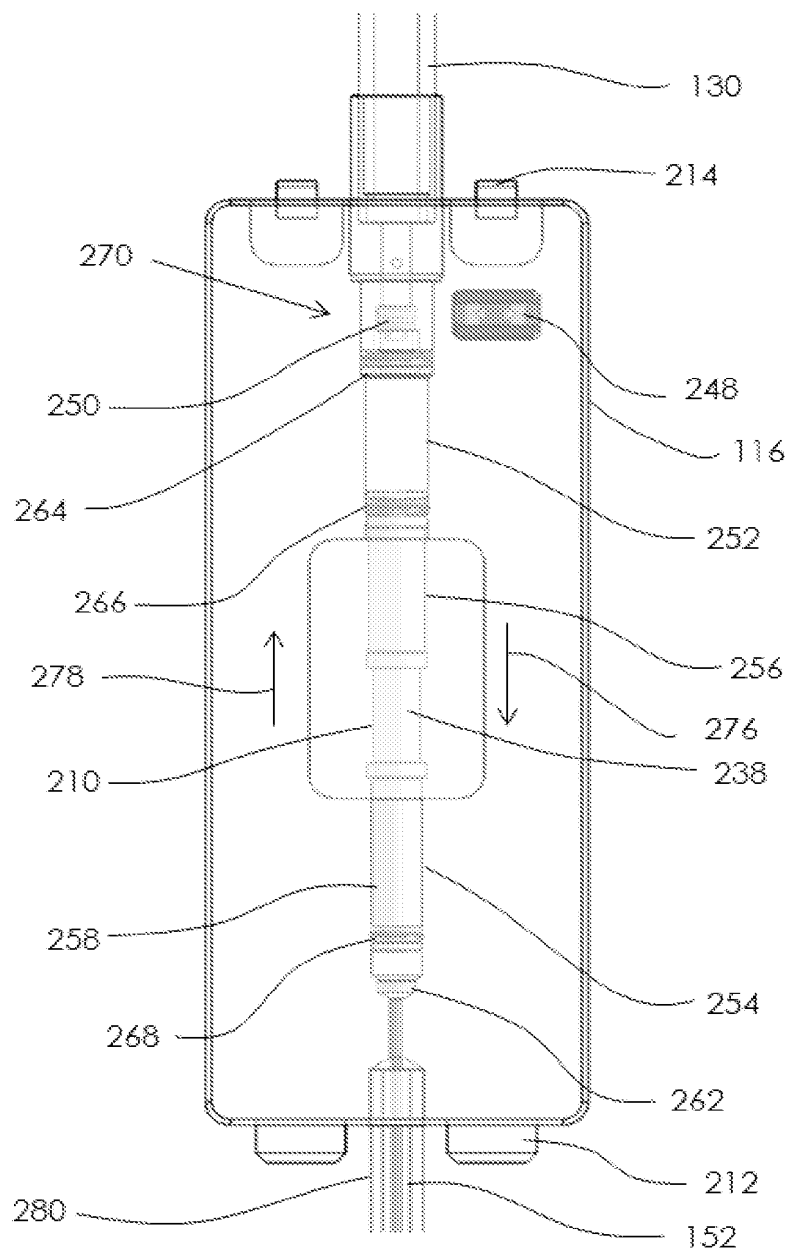


FIG. 15

12/20

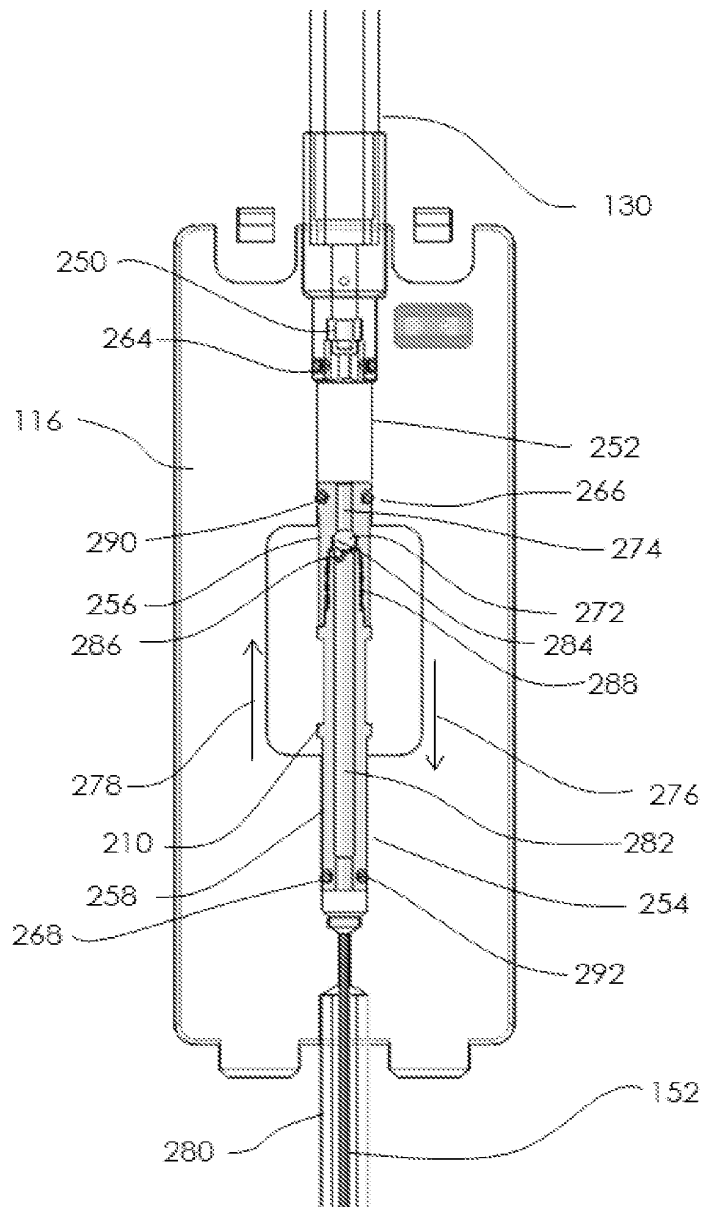
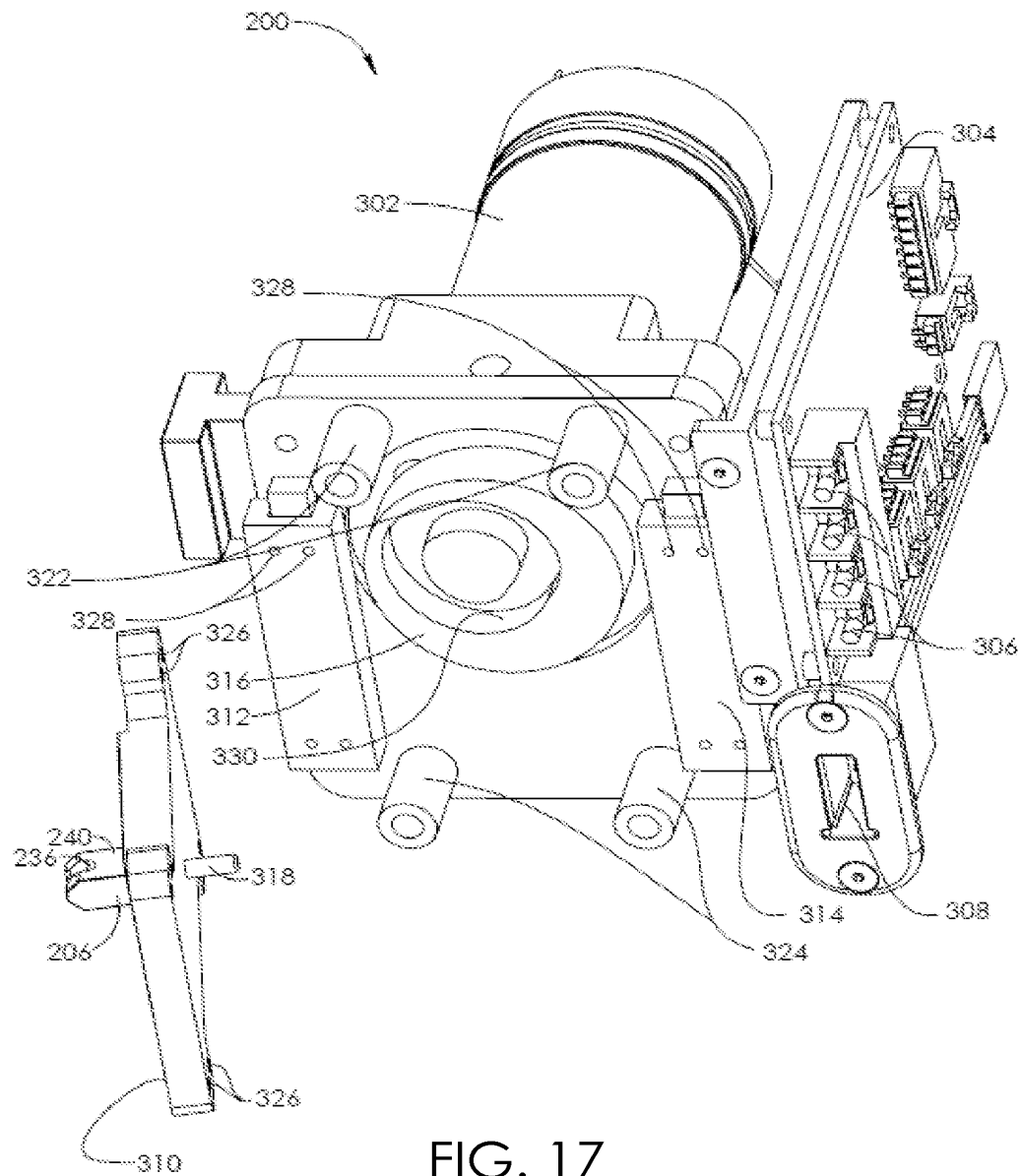


FIG. 16

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14/20

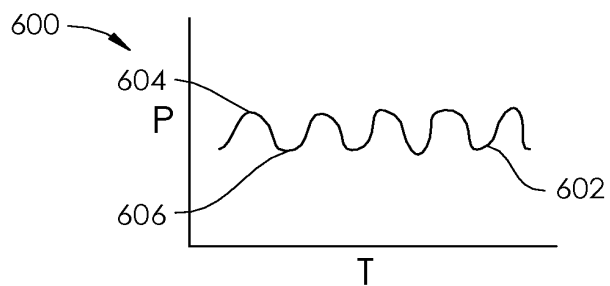


FIG. 18

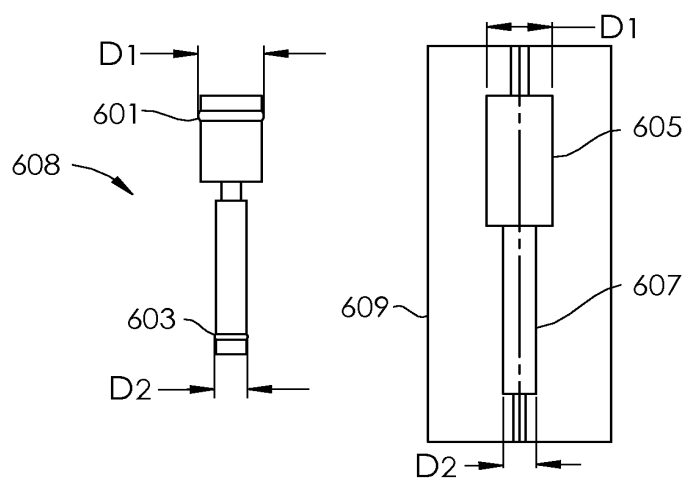


FIG. 19

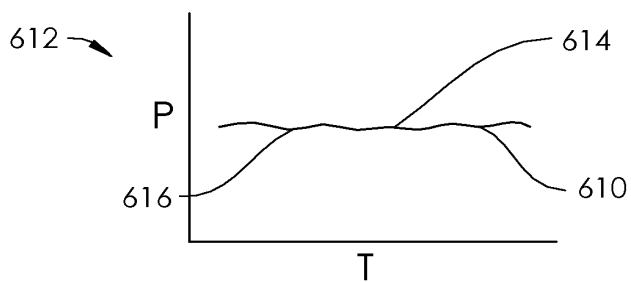


FIG. 20

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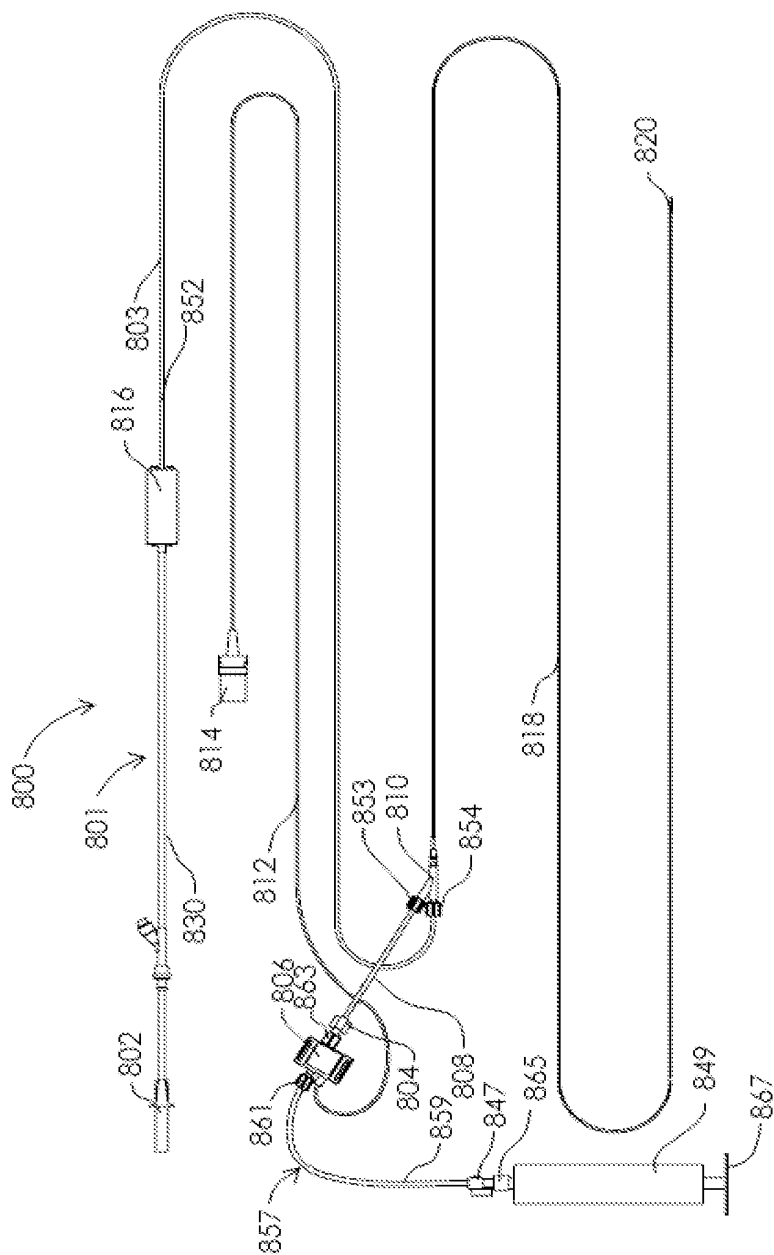


FIG. 21

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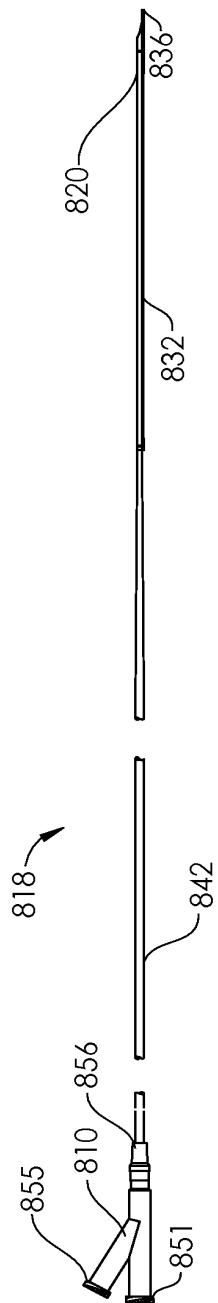


FIG. 22

17/20

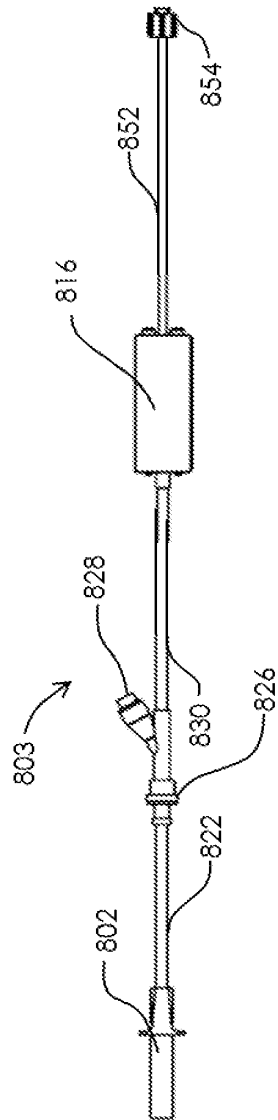


FIG. 23

18/20

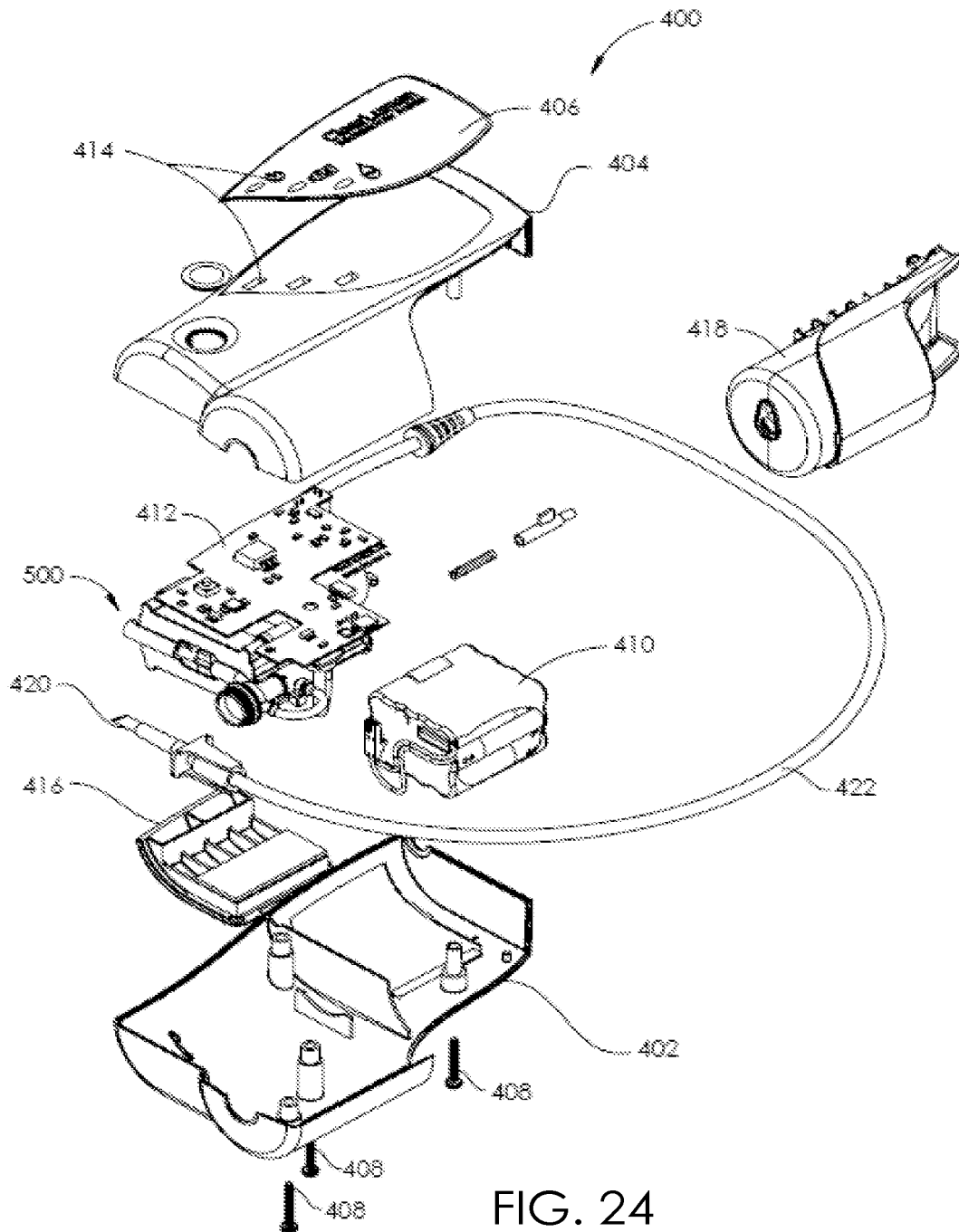
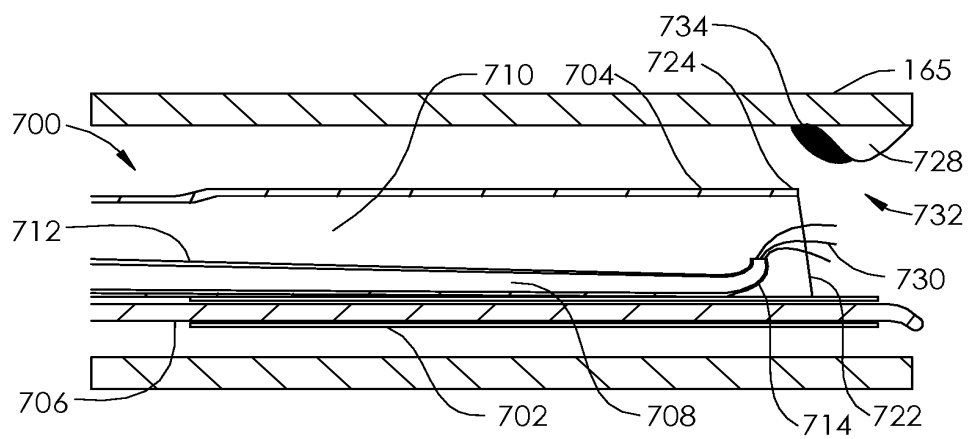
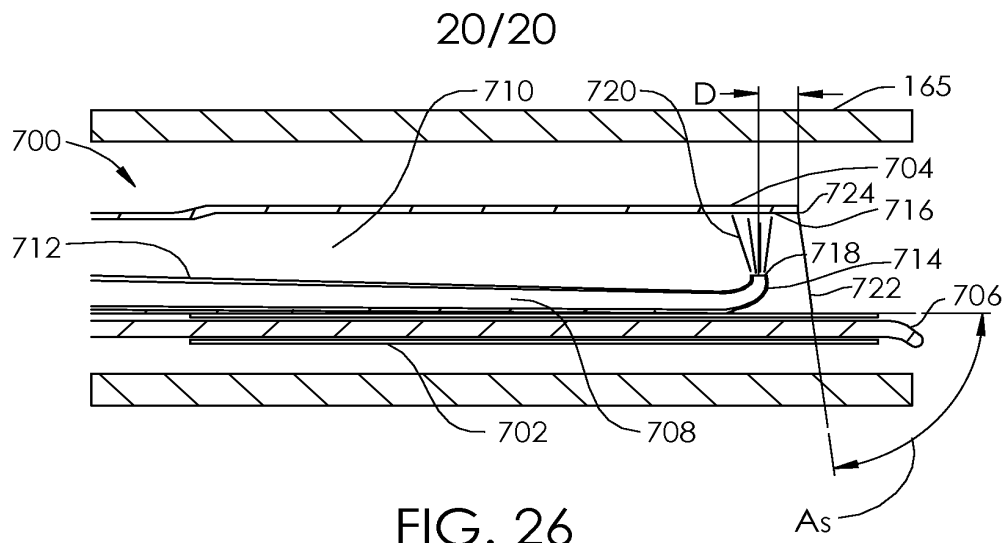


FIG. 24



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/31460

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 1/00 (2015.01)

CPC - A61M 1/0084, A61M 25/003, A61M 1/0023, A61M 2039/082

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)

IPC(8) - A61M 1/00 (2015.01)

CPC - A61M 1/0084, A61M 25/003, A61M 1/0023, A61M 2039/082

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
604/508, 266-269 (UPC)

(Search term limited; see below)

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

PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);

Search Terms: Aspirat*, suction*, vacuum*, drain*, catheter*, conduit, lumen, tube, jet, nozzle, spray, clog*, unclog*, declog*, obstruct*, anticlog*, antiobstr*, rinse, flush*, clean*, clear*, pump*, motor*, driv*, piston*, valve, one way, thromb*, blood

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 1990/05493 A1 (SVEDMAN) 31 May 1990 (31.05.1990) Entire document, especially p3, ln 10 - p4, ln 27, p5, ln 11-30 and FIGS. 1, 4.	1-20
Y	US 3,429,313 A (ROMANELLI) 25 February 1969 (25.02.1969) Entire document, especially col 3, ln 10- col 4, ln 5, col 6, ln 67- col 7, ln 4 and FIG. 1.	1-3, 6-7, 10-20
Y	US 3,707,967 A (KITRILAKIS et al.) 02 January 1973 (02.01.1973) Entire document, especially Abstract, col 3, ln 44- col 4, ln 34 and FIGS. 1, 4.	1, 4-5, 8-9
A	US 2012/0289910 A1 (SHTUL et al.) 15 November 2012 (15.11.2012) Entire document.	1-20
A	US 5,713,849 A (BOSMA et al.) 03 February 1988 (03.02.1988) Entire document.	1-20
A	US 4,690,672 A (VELTRUP) 01 September 1987 (01.09.1987) Entire document.	1-20
A	US 3,916,892 A (HANSEN et al.) 11 May 1976 (11.05.1976) Entire document.	1-20
A	US 2,804,075 A (BORDEN) 27 August 1957 (27.08.1957) Entire document.	1-20

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"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

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Date of the actual completion of the international search

16 July 2015 (16.07.2015)

Date of mailing of the international search report

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Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 6799

FILED BY JiYoung Anderson

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CUSTOMER # 25096

FIRST NAMED
INVENTOR Ben Merritt

CORRESPONDENCE
ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-7-24 IDS SB08 - 111552-8018US11.PDF	2	Information Disclosure Statement (IDS) Form (SB08)	121 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_JP_Office Action 2021- 507564_mailed June 7, 2023, 7 pages.PDF	7	Non Patent Literature	94 KB
FOR_WO2015179329.PDF	56	Foreign Reference	2433 KB
FOR_WO2023137341.PDF	75	Foreign Reference	3594 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-24 IDS SB08 - 111552-8018US11.PDF	6229249FE64CCC8E27E90207830ED90BB1B944CBC72186C296F1D9C5E33FBDB404E5D45300CB2CB7FBE6404D4975ED2A0BFB2D0154BEB3CC256782927A62CEF4
NPL_JP_Office Action 2021-507564_mailed June 7, 2023, 7 pages.PDF	2272FDE0C8B9D6C2C654816392741B6A54B81145D6CBA5D05CEC760E93C77634AC3C6903081FC18F1F3B3760D1DF5869AB3A21DEA3EB50D59B10DF35C6D21826
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FOR_WO2023137341.PDF	0EED4348CDC2BC929DF5488A6BB3299B1CF492244B5F17616256350DF062C9C554456D996FCC48B4DE6BB3EEAC7495B02274727C8C04E2B6D5366DA5E9C17349

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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

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(54) Title: DEVICES FOR REMOVING CLOT MATERIAL FROM INTRAVASCULARLY IMPLANTED DEVICES, AND ASSOCIATED SYSTEMS AND METHODS

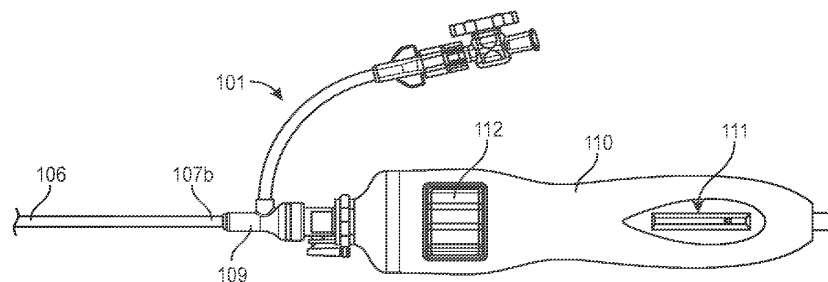


FIG. 1A

(57) Abstract: Disclosed herein are devices for mechanically removing clot and/or other material from implants implanted in the vasculature of a patient, and associated systems and methods. In some embodiments, a system for removing clot material from an implant—such as a stent—includes a clot treatment device configured to be deployed within the stent, a handle, and a first elongate member and a second elongate member coupling the clot treatment device to the handle. The first elongate member couples a first end portion of the clot treatment device to the handle, and the second elongate member couples a second end portion of the clot treatment device to an actuator of the handle. Actuation of the actuator is configured to move the second elongate member relative to the first elongate member to move the first and second end portions toward one another to radially expand the clot treatment device.

WO 2023/137341 A1

DEVICES FOR REMOVING CLOT MATERIAL FROM
INTRAVASCULARLY IMPLANTED DEVICES,
AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No.63/298,399, filed January 11, 2022, and titled “DEVICES FOR REMOVING CLOT MATERIAL FROM INTRAVASCULARLY IMPLANTED STENTS, AND ASSOCIATED SYSTEMS AND METHODS,” which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to devices for cleaning stents, embolic protection devices, other implants, and/or bare vessels and, more particularly, for example, to devices for intravascularly removing clot and/or other material from stents implanted in the vasculature of a patient (e.g., the venous vasculature).

BACKGROUND

[0003] Stents are tubes or similar structures that can be implanted within a blood vessel of a patient to mechanically keep the vessel open, restore flow, and/or bypass a diseased region of the blood vessel. Stents are typically made of metal or plastic, and can be crimped or packed down into a delivery catheter before being intravascularly delivered to a target location within the blood vessel.

[0004] After a stent is delivered to and implanted within a blood vessel of a patient, unwanted material can form around and/or adhere to the stent. For example, clot material can form and adhere to an inner surface of the stent. Similarly, vascular wall cells can abnormally accumulate within the stent (e.g., intimal hyperplasia).

[0005] Physicians are currently limited in their abilities to remove adherent clot or intimal hyperplasia from implanted stents and, in particular, venous stents. For example, while aspiration mechanisms exist to remove clot material from venous stents, these aspiration mechanisms are limited to non-adherent, acute clot, and cannot treat chronic adherent clot or intimal hyperplasia. Further, while mechanical clot treatment devices exist to target adherent

clot material, many such devices are currently contraindicated for removing clot material from stents because the mechanical clot treatment devices can catch on the stent, causing damage. Other methods of medical management such as ballooning or re-stenting do not remove the clot that has been formed, likely causing additional clot to form. Pharmacological methods—such as administering tissue plasminogen activator (tPA)—do not work on aged, more adherent clot, and also carry other risks such as systemic bleeding. Surgery carries risks of adverse events and is more invasive than transcatheter methods.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0007] Figure 1A is a side view of a stent cleaning system in accordance with embodiments of the present technology. Figures 1B and 1C are an enlarged side view and an enlarged proximally-facing view, respectively, of a distal portion of the system of Figure 1A including a clot treatment device in accordance with embodiments of the present technology.

[0008] Figures 2A–2C are enlarged proximally-facing views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

[0009] Figures 3A–3D are enlarged side views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

[0010] Figures 4A–4C are enlarged isometric views of a distal portion of the system of Figure 1A including the clot treatment device in accordance with additional embodiments of the present technology.

[0011] Figure 5 is a partially cut-away view of a handle of the system of Figure 1A in accordance with embodiments of the present technology.

[0012] Figures 6A and 6B are side views of a distal portion of the system of Figure 1A including the clot treatment device in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0013] Figure 7 is a flow diagram of a process or method for operating the system of Figure 1A during an intravascular procedure to remove clot material from an implanted stent in accordance with embodiments of the present technology.

[0014] Figure 8 is a distally-facing perspective view of a distal portion of the system of Figure 1A including the clot treatment device expanded within a stent implanted in a vessel in accordance with embodiments of the present technology.

[0015] Figures 9A and 9B are distally-facing perspective views of a distal portion of the system of Figure 1A including the clot treatment device positioned within the stent of Figure 6 in accordance with embodiments of the present technology.

[0016] Figures 10A–10C are distally-facing perspective views of a distal portion of the system of Figure 1A including the clot treatment device deployed within an implant with differing amounts of radial expansion in accordance with embodiments of the present technology.

[0017] Figure 11A is a side view of a stent cleaning system in accordance with embodiments of the present technology. Figures 11B and 11C are side views of a distal portion of the system of Figure 11A including a clot treatment device in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0018] Figure 12 is a side view of a clot treatment device in accordance with embodiments of the present technology.

[0019] Figure 13 is a side view of a clot treatment device in accordance with embodiments of the present technology.

[0020] Figure 14 is a side view of a clot treatment device in accordance with embodiments of the present technology.

[0021] Figure 15 is a side view of a clot treatment device in accordance with embodiments of the present technology.

[0022] Figures 16A–16C are side views of a clot treatment device in accordance with embodiments of the present technology.

[0023] Figures 17A and 17B are side views of a distal portion of a stent cleaning system in accordance with embodiments of the present technology.

[0024] Figure 18 illustrates several different chamfers that can be used in a clot treatment device in accordance with embodiments of the present technology.

[0025] Figure 19 is an enlarged side view of a pair of struts of a clot treatment device in accordance with embodiments of the present technology.

[0026] Figure 20 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0027] Figure 21 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0028] Figure 22 is a side cross-sectional view of an actuation mechanism of a handle in accordance with embodiments of the present technology that can be used in the system of Figure 1A.

[0029] Figure 23 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0030] Figure 24 is a side cross-sectional view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0031] Figures 25A–25C are an enlarged perspective view, an enlarged side view, and an enlarged cross-sectional side view, respectively, of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0032] Figure 26 is an enlarged cross-sectional side view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0033] Figure 27 is an enlarged cross-sectional side view of a handle in accordance with additional embodiments of the present technology that can be used in the system of Figure 1A.

[0034] Figure 28 is a side view of a distal portion of a clot removal system positioned within a vessel to treat clot material in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0035] The present technology is generally directed to devices for mechanically removing clot and/or other material from the vasculature of a patient, and associated systems and methods. In particular, some of the embodiments are directed to devices for mechanically removing clot and/or other material from implants implanted in the vasculature of the patient, such as stents

implanted within the venous vasculature. In some embodiments described below, a system for removing clot material from an implant—such as a venous stent—includes a (i) clot treatment device, (ii) a handle, and (iii) a first elongate member and a second elongate member coupling the clot treatment device to the handle. The clot treatment device is configured to be deployed within the implant, and includes a first end portion, a second end portion, and a plurality of struts extending between the first and second end portions. The first elongate member couples the first end portion of the clot treatment device to the handle, and the second elongate member couples the second end portion of the clot treatment device to the handle (e.g., to an actuator of the handle). Actuation of the actuator in a first direction is configured to move the second elongate member relative to the first elongate member and/or the first elongate member relative to the second elongate member to move the first and second end portions toward one another to radially expand the struts. The actuator can be actuated in a second direction (e.g., opposite the first direction) to move the second elongate member relative to the first elongate member and/or the first elongate member relative to the second elongate member to move the first and second end portions away from one another to radially collapse the struts.

[0036] When expanded within the implant, the clot treatment device can be (i) translated proximally and/or distally through the implant by translating the handle and (ii) rotated within the implant by rotating the handle. Such movements can mechanically engage the clot treatment device with clot material adhered to the implant to dislodge the clot material. In some aspects of the present technology, the clot treatment device is configured to be translated and/or rotated within the implant without catching on the implant, avoiding potential damage, deformation, movement, and/or migration of the implant. For example, the struts can extend generally axially between the first and second end portions—and not include any cross-members connected therebetween that are configured to contact the implant—to reduce the likelihood of the struts damaging the implant.

[0037] Certain details are set forth in the following description and in Figures 1–28 to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, stents, vascular implants, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so

forth. Moreover, although many of the devices and systems are described herein in the context of removing and/or treating clot material (e.g., clot material adhered to an implant), the present technology can be used to remove and/or treat other unwanted material in addition or alternatively to clot material, such as thrombi, emboli, plaque, intimal hyperplasia, post-thrombotic scar tissue, etc. Accordingly, the terms “clot” and “clot material” as used herein can refer to any of the foregoing materials.

[0038] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, 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.

[0039] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

[0040] With regard to the terms “distal” and “proximal” within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations “rearward,” “forward,” “upward,” “downward,” and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user. To the extent any materials incorporated herein by reference conflict with the present disclosure, the present disclosure controls.

[0041] Figure 1A is a side view of a stent cleaning system 100 (“system 100”) in accordance with embodiments of the present technology. Figures 1B and 1C are an enlarged side view and an enlarged proximally-facing view, respectively, of a distal portion of the system 100 including a clot treatment device 130 in accordance with embodiments of the present technology. The stent cleaning system 100 can be used to remove clot material from (e.g., adhered to) the implant, to clean clot material from a native vessel in which the implant is implanted, and/or to remove clot material from a native vessel in which no implants are implanted. Accordingly, the system 100 can also be referred to as a clot treatment system, a clot removal system, a thrombectomy system, and/or the like. The clot treatment device 130 can also be referred to as a clot removal device, a coring element, a clot engagement member, a thrombectomy device, and/or the like.

[0042] Referring to Figures 1A and 1B together, in the illustrated embodiment the system 100 includes a proximal handle 110 operably coupled to a clot treatment device 130 via an inner elongate member 102 (obscured in Figure 1A; e.g., a second elongate member) and a middle elongate member 104 (e.g., a first elongate member). The inner elongate member 102 can extend through a lumen of the middle elongate member 104 such that the inner and middle elongate members 102, 104 (collectively “elongate members 102, 104”) are coaxial. The system 100 can further include an outer elongate member 106 (e.g., a third elongate member, a guide catheter), and the elongate members 102, 104 can at least partially extend through the outer elongate member 106 such that the inner, middle, and outer elongate members 102, 104, 106 (collectively “elongate members 102–106”) are coaxial. In other embodiments, the elongate members 102, 104 are not coaxial and can instead extend side-by-side and/or through separate lumens of the outer elongate member 106. The elongate members 102–106 can comprise catheters, tubes (e.g., hypotubes), sheaths, shafts, and/or the like and can be formed from metal (e.g., stainless steel, nitinol), plastic, fluoropolymers (e.g., polytetrafluoroethylene (PTFE)), polymers, and/or other suitable materials. The outer elongate member 106 can comprise a guide catheter.

[0043] Referring to Figure 1A, the outer elongate member 106 can include a distal end portion 107a and a proximal end portion 107b. The proximal end portion 107b can be coupled to a tubing assembly 101 (e.g., including one or more tubes, fluid control devices, and/or the like) via a valve device 109. In some embodiments, the tubing assembly 101 can be used to flush the lumen of the outer elongate member 106. In some embodiments, the handle 110 is movable (translatable, rotatable) relative to the valve device 109 and the outer elongate member 106. In the illustrated embodiment, the handle 110 has been advanced toward the valve device

109 such that the clot treatment device 130 extends from the distal end portion 107a of the outer elongate member 106. In some embodiments, the handle 110 can be retracted away from the outer elongate member 106 and/or the outer elongate member 106 can be advanced away from the handle 110 such that the clot treatment device 130 is captured/positioned within the outer elongate member 106. When the clot treatment device 130 is captured within the lumen of the outer elongate member 106, the clot treatment device 130 is in a radially-compressed state. In some embodiments, the clot treatment device 130 can be positioned within the outer elongate member 106 during delivery of the system 100 through the vasculature.

[0044] In the illustrated embodiment, the system 100 includes a tip 108 coupled to the clot treatment device 130 and/or the inner elongate member 102 (Figure 1B). The tip 108 can have an atraumatic shape configured to minimize or even prevent damage to the vasculature as the system 100 is advanced therethrough. In other embodiments, the tip 108 can have other shapes or can be omitted entirely. In some embodiments, when the clot treatment device 130 is constrained within the outer elongate member 106, the tip 108 can engage the distal end portion 107a of the outer elongate member 106 and can be shaped and sized to seal the lumen of the outer elongate member 106. In some embodiments, the tip 108 and the inner elongate member 102 (Figure 1B) can define a lumen configured (e.g., shaped and sized) to receive a guidewire (not shown) therethrough. The system 100 can be advanceable/trackable over the guidewire.

[0045] Referring to Figure 1B, in the illustrated embodiment the inner elongate member 102 includes a distal end portion 103a coupled to a distal end portion 131a of the clot treatment device 130. Similarly, the middle elongate member 104 includes a distal end portion 105a coupled to a proximal end portion 131b of the clot treatment device 130. Accordingly, as described in detail below with reference to Figures 6A and 6B, relative movement of the elongate members 102, 104 can longitudinally shorten/lengthen and radially expand/compress the clot treatment device 130 via the relative movement of the end portions 131a-b. The end portions 131a-b of the clot treatment device 130 can be identical and can have a cylindrical or hub-like shape. In some embodiments, the end portions 131a-b are secured to the elongate members 102, 104, respectively, via adhesive (e.g., glue bonds), welding, fasteners, crimping (e.g., via a crimp tube), and/or the like. For example, in some embodiments one or both of the end portions 131a-b of the clot treatment device 130 can be directly welded to the elongate members 102, 104, or one or both of the end portions 131a-b can be crimped via a crimp tube to the elongate members 102, 104 (e.g., the proximal end portion 131b can be crimped to the middle elongate member 104). In some embodiments, the distal end portion 131a includes/defines a distal window 132a

extending therethrough, and the proximal end portion 131b includes/defines a proximal window 132b extending therethrough. Coupling members (not shown), such as steel discs, can be placed in one or both of the windows 132a-b and welded, soldered, crimped, or otherwise fastened to the elongate members 102, 104, respectively, to secure the end portions 131a-b to the elongate members 102, 104 via a rivet-like lock. In some embodiments, the end portions 131a-b can include multiple ones of the windows 132a-b extending circumferentially thereabout, each configured to receive a corresponding coupling member.

[0046] The elongate members 102, 104 can comprise (i) metal, polymeric, and/or metallic (e.g., solid stainless steel, cobalt chrome, nitinol) tubes, (ii) metal, polymeric, and/or metallic (e.g., solid stainless steel, cobalt chrome, nitinol) tubes with relief cuts (e.g., laser-cuts) for flexibility, (iii) hollow helical spirals (e.g., including one or more axial metal (e.g., stainless-steel, cobalt chrome, nitinol) wires turned to create a closed-pitch coil with a hollow central lumen), (iv) reinforced polymeric shafts, and/or (v) the like. In the illustrated embodiment, for example, the inner elongate member 102 comprises a solid nitinol tube and the middle elongate member 104 comprises a hollow helical spiral (HHS). The hollow helical spiral can be a single layer spiral, or a multilayer spiral (e.g., two-layer, three-layer, or more layer spiral) to provide greater torque and/or tensile response. In some aspects of the present technology, such a hollow helical spiral allows the overall system 100 to be more flexible such that the system 100 can, for example, be inserted to treat clot material in more tortuous anatomies with less biasing of the clot treatment device 130 (e.g., to one side of an implant or vessel). In some aspects of the present technology, the elongate members 102, 104 can have a relatively high tensile, compression, and/or torque capability/response that allow for the controlled expansion and movement of the clot treatment device 130 during a procedure to remove clot material from an implanted stent, embolic protection device, other implant, and/or bare vessel, as described in greater detail below.

[0047] Referring to Figures 1B and 1C together, the clot treatment device 130 includes a plurality of beams or struts 133 extending between the end portions 131a-b and generally axially relative to a longitudinal axis L of the clot treatment device 130. More specifically, the struts 133 can be generally similar or identical to one another and can each include: (i) a distal portion 134 extending from the distal end portion 131a in a direction away from the longitudinal axis L and proximally toward the proximal end portion 131b (e.g., at an angle relative to the longitudinal axis L), (ii) a middle portion 135 extending from the distal portion 134 proximally and generally parallel to the longitudinal axis L, and (iii) a proximal portion 136 extending from

the middle portion 135 to the proximal end portion 131b in a direction toward the longitudinal axis L (e.g., at an angle relative to the longitudinal axis L). In the illustrated embodiment, the clot treatment device 130 does not include any cross struts or other cross-members extending between (e.g., circumferentially between) the struts 133. That is, the struts 133 can each extend separately in a generally axial direction between the end portions 131a-b. In some aspects of the present technology, this absence of cross struts can permit the clot treatment device 130 to be advanced and retracted through an implanted stent (or other implant) without catching on the stent (e.g., catching on apices or ends of the stent), which could potentially damage, disrupt, and/or move the stent. In some embodiments, the clot treatment device 130 can include one or more cross-members between the struts 133—but that are not configured to contact the implanted stent when the clot treatment device 130 is expanded. For example, such cross-members can be positioned near the end portions 131a-b.

[0048] As best seen in Figure 1B, in the illustrated embodiment the struts 133 each have an undulating (e.g., wave-like, sawtooth-like, periodic) pattern. The undulating pattern of the struts 133 can create an abrasive surface for disrupting/engaging with clot and/or other material adhered to an implanted stent. More specifically, because of the undulating pattern, each of the struts 133 can include one or circumferential portions 137 that extend at least partially circumferentially relative to the longitudinal axis L. The circumferential portions 137 can together define the abrasive surface for disrupting the clot material. In some aspects of the present technology, the undulations are relatively small such to reduce the likelihood of the struts 133 catching on the stent when the clot treatment device 130 is advanced and retracted through the implanted stent.

[0049] As best seen in Figure 1C, each of the struts 133 can curve radially at least partially back toward the longitudinal axis L in the middle portion 135 (and/or at a transition region between the middle portion 135 and distal and proximal portions 134, 136) such that the struts 133 have a wave-like or hook-like shape when viewed along the longitudinal axis L. In some embodiments, this shape can help facilitate the uniform collapse of the clot treatment device 130. In additional aspects of the present technology, the hook-like shape of the struts 133 can improve the ability of the clot treatment device 130 to engage and disrupt clot material within an implant while still being atraumatic to regions of the native vessel outside the implant (e.g., proximal and distal of the implant).

[0050] The clot treatment device 130 has nine of the struts 133 in Figure 1B and six of the struts 133 in Figure 1C for illustration. In other embodiments, the clot treatment device 130 can include any number of the struts 133 (e.g., one, two, three, four, five, seven, eight, ten, or more than ten) and the struts 133 can be positioned symmetrically or asymmetrically about the longitudinal axis L. For example, in some embodiments the struts 133 can be asymmetrically positioned about the longitudinal axis L to facilitate targeted engagement of the struts 133 with a region of adherent clot and/or to inhibit or even prevent catching of the clot treatment device 130 on bent portions of an implant (e.g., when the implant is positioned within tortuous anatomy). In some embodiments, the distal portions 134 of the struts 133 can be circumferentially offset from the proximal portions 136 of the struts 133—either permanently or via differential rotation of the elongate members 102, 104—to cause the struts 133 to assume a “scoop-like” shape when radially compressed, as described in greater detail below with reference to Figures 10A–10C. That is, for example, the distal portion 134 of each of the struts 133 can connect to the distal end portion 131a at a different circumferential position (e.g., relative to the longitudinal axis L) than the proximal portion 136 of the strut 133 connects to the proximal end portion 131b.

[0051] In some embodiments, the clot treatment device 130 is an integral/continuous structure, such as a laser-cut metal (e.g., nitinol, cobalt chrome, stainless steel) element. In some embodiments, the clot treatment device 130 is configured (e.g., heat set) to self-expand from a compressed delivery state (e.g., when the clot treatment device 130 is positioned within the outer elongate member 106) to the expanded deployed state illustrated in Figures 1B and 1C. In other embodiments, the clot treatment device 130 is configured (e.g., heat set) to collapse to the compressed delivery state from the expanded state. In such embodiments, biasing the clot treatment device 130 to collapse can help ensure that the clot treatment device 130 can be removed from the patient if one of the struts 133 or a connection point breaks during operation, as the clot treatment device 130 will automatically collapse for removal.

[0052] In some embodiments, the struts 133 can curve more or less back toward the longitudinal axis L. Figures 2A–2C, for example, are enlarged proximally-facing views of a distal portion of the system 100 including the clot treatment device 130 in accordance with additional embodiments of the present technology. Referring to Figures 2A–2C together, the middle portion 135 of each of the struts 133 of the clot treatment device 130 has (i) a relatively flat profile in the embodiment of Figure 2A, (ii) a hook-shaped profile in the embodiment of Figure 2B, and (iii) a further hook-shaped profile in the embodiment of Figure 2C. In some

aspects of the present technology, (i) the flatter profile shown in Figure 2A can provide a longer cutting edge for engaging clot material adhered to an implant, (ii) the more hook-shaped profile shown in Figure 2B can provide for a smaller contact area between the clot treatment device 130 and an implant that can reduce the likelihood of the clot treatment device 130 damaging the implant and that can be more atraumatic to a native vessel when the clot treatment device 130 is deployed at least partially outside the implant, and (iii) the further hook-shaped profile shown in Figure 2C can provide an even smaller cutting surface than the profile shown in Figure 2B to further reduce the likelihood of implant or native vessel damage as compared to the profile of Figure 2B. In some embodiments, the flatter profile shown in Figure 2A can be utilized to treat adherent clot material that is firmly attached to the implant.

[0053] Similarly, in other embodiments one or more of the struts 133 can have different shapes and/or profiles. For example, Figures 3A–3D are enlarged side views of a distal portion of the system 100 including the clot treatment device 130 in accordance with additional embodiments of the present technology. In some embodiments, as shown in Figure 3A, the tip 108 (Figure 3B) can be omitted and the struts 133 can extend to and past the distalmost end of the inner elongate member 102 in the expanded position. As shown in Figure 3B, one or more of the struts 133 can have a profile including multiple (e.g., two) bumps or peaks between the end portions 131a-b. As shown in Figure 3C, one or more of the struts 133 can have an axial apex positioned near the distal end portion 131a (e.g., including a proximal tapered portion). As shown in Figure 3D, one or more of the struts 133 can have an axial apex positioned near the proximal end portion 131b (e.g., including a distal tapered portion).

[0054] Further, Figures 4A–4C are enlarged isometric views of a distal portion of the system 100 including one of the struts 133 of the clot treatment device 130 in accordance with additional embodiments of the present technology. As shown in Figure 4A, one or more of the struts 133 can have a profile including multiple (e.g., two) bumps or peaks between the end portions 131a-b and that does not extend radially about the longitudinal axis L and the inner elongate member 102 (Figure 1B). As shown in Figure 4B, one or more of the struts 133 can have a profile including a smoothly sloping shape between the distal and proximal end portions 131a-b. As shown in Figure 4C, one or more of the struts 133 can extend radially about (e.g., spiral about) the longitudinal axis L and the inner elongate member 102 (Figure 1B) between the end portions 131a-b.

[0055] Figure 5 is a partially cut-away view of the handle 110 of Figure 1A in accordance with embodiments of the present technology. In the illustrated embodiment, the handle 110 includes a housing 514 having a distal portion 515a and a proximal portion 515b and defining an internal chamber or lumen 516. The housing 514 is shown as partially-cut away in Figure 5 for clarity. A proximal portion 105b of the middle elongate member 104 can be fixedly coupled to the distal portion 515a of the housing 514. In some embodiments, the handle 110 includes a flush port 517 operably (e.g., fluidly) coupled to the lumen of the middle elongate member 104. The inner elongate member 102 can extend through the lumen of the middle elongate member 104, past the proximal portion 105b of the middle elongate member 104, and into the lumen 516 of the housing 514. In some embodiments, the inner elongate member 102 can extend entirely through the housing 514 to a flush port 518 coupled to the proximal portion 515 of the housing 514.

[0056] In the illustrated embodiment, the handle 110 further comprises a leadscrew 520 attached to the inner elongate member 102 and movably positioned within the lumen 516 over one or more guiderails 522 (e.g., a pair of guiderails 522). The leadscrew 520 can have a threaded outer surface configured to mate with a threaded inner surface of the actuator 112 (shown as partially transparent in Figure 5 for clarity). Alternatively, the leadscrew 520 can have a threaded inner surface configured to mate with a threaded outer surface of the actuator 112 as described, for example, in detail below with reference to Figure 26. The actuator 112 can extend out of the housing 514 from one or more openings 519 therein (e.g., a pair of openings on opposing sides of the housing 514) such that the actuator 112 is accessible outside the housing 514 by a user of the handle 110 (e.g., a physician). In some embodiments, the handle 110 further includes a leadscrew knob 521 (shown as partially transparent in Figure 2 for clarity) coupled to the actuator 112 and configured to threadably engage the leadscrew 520 over an entire range of movement of the actuator 112.

[0057] Rotation of the actuator 112 relative to the housing 514 (e.g., by the user) can drive the leadscrew 520 to translate proximally and/or distally (e.g., between the distal and proximal portions 515a-b of the housing 514) to thereby drive the attached inner elongate member 102 to translate relative to the middle elongate member 104. This relative movement of the elongate members 102, 104 lengthens/shortens the clot treatment device 130 (Figures 1A–1C) to radially compress/expand the clot treatment device 130. More specifically, Figures 6A and 6B are side views of a distal portion of the system 100 including the clot treatment device 130 in a first position (e.g., a radially-expanded position) and a second position (e.g., a radially-compressed

position), respectively, in accordance with embodiments of the present technology. Referring to Figures 5–6B together, in the first position (Figure 6A) the clot treatment device 130 is radially expanded, having a first diameter D_1 and a first length X_1 , and in the second position the clot treatment device 130 is radially compressed, having a second diameter D_2 less than the first diameter D_1 and a second length X_2 greater than the first length X_1 . In both the first and second positions the clot treatment device 130 has been advanced distally out of the outer elongate member 106 (e.g., past the distal end portion 107a thereof).

[0058] To move the clot treatment device 130 from the first position to the second position, the user can rotate the actuator 112 in a first direction to drive the leadscrew 520 distally through the housing 514. This movement drives the inner elongate member 102 distally through the lumen of the middle elongate member 104, thereby driving the distal end portion 131a of the clot treatment device 130 distally relative to the proximal end portion 131b to radially compress the clot treatment device 130 while lengthening the clot treatment device 130. Conversely, to move the clot treatment device 130 from the second position to the first position, the user can rotate the actuator 112 in a second direction opposite the first direction to drive the leadscrew 520 proximally through the housing 514. This movement drives the inner elongate member 102 proximally through the lumen of the middle elongate member 104, thereby driving the distal end portion 131a of the clot treatment device 130 proximally relative to the proximal end portion 131b to radially expand the clot treatment device 130 while shortening the clot treatment device 130. Although two discrete positions are shown in Figures 6A and 6B, the clot treatment device can be expanded to any number of continuous positions therebetween, to a position further radially expanded than the first position, and/or to a position less radially expanded than the second position. Moreover, in other embodiments the middle elongate member 104 can be operably coupled to the leadscrew 520 and the actuator 112 instead of or in addition to the inner elongate member 102 such that actuation of the actuator 112 drives the middle elongate member 104 relative to the inner elongate member 102, or both the inner elongate member 102 and the middle elongate member 104 relative to the handle 110, to radially expand/compress the clot treatment device 130.

[0059] Referring to Figure 1A, in some embodiments the handle 110 can further include an indicator 111, such as a slider, configured to provide a visual indication of an amount of radial expansion of the clot treatment device 130. The indicator 111 can, for example, indicate whether the clot treatment device 130 is in the first position or the second position. In some embodiments, the indicator 111 includes detents and/or other features that provide an indication (e.g., a

“clicking” sound) as the clot treatment device 130 is incrementally expanded/collapsed (e.g., millimeter by millimeter). Similarly, the indicator 111 can include markings that indicate an expanded size of the clot treatment device 130 as described in, for example, detail below with reference to Figures 25A–26.

[0060] Referring to Figures 1A–1C together, in other embodiments a handle of the system 100 can include a first member coupled to the inner elongate member 102 and a second member coupled to the middle elongate member 104. One or both of the first and second members can be manually moved relative to one another (e.g., without any mechanical advantage provided by a leadscrew, gear, or the like) to radially expand/compress the clot treatment device 130 as shown in Figures 6A and 6B.

[0061] Figure 7 is a flow diagram of a process or method 740 for operating the system 100 during an intravascular procedure to remove material from an implant with a patient in accordance with embodiments of the present technology. Although some features of the method 740 are described in the context of the embodiments shown in Figures 1A–6B for the sake of illustration, one skilled in the art will readily understand that the method 740 can be carried out using other suitable systems and/or devices described herein.

[0062] At block 741, the method 740 can include advancing the system 100 through the vasculature of a patient to at or proximate the implant implanted within the patient. The implant can be identified as having clot material or other unwanted material (e.g., intimal hyperplasia) adhered thereto that would be beneficial to remove. In some embodiments, the implant is a stent implanted within the venous vasculature of the patient. In other embodiments, the implant can be a graft, embolic filter, inferior vena cava (IVC) filter, and/or other type of implant. In other embodiments, the method 740 can be used to clean and remove clot material from a bare vessel of the patient. In some embodiments, the elongate members 102–106 can be advanced together through the vasculature with the clot treatment device 130 constrained within the outer elongate member 106. The tip 108 can provide for atraumatic advancement of the system 100 through the vasculature to the implant. In other embodiments, the outer elongate member 106 can be positioned within the vasculature first, and the clot treatment device 130 can then be advanced through the vasculature to the implant.

[0063] At block 742, the method 740 can include deploying the clot treatment device 130 within the implant. For example, the handle 110 can be advanced distally (e.g., pushed by a physician) relative to the outer elongate member 106 to advance the elongate members 102, 104

and the coupled clot treatment device 130 distally from the distal end portion 107a of the outer elongate member 106. In some embodiments, the clot treatment device 130 can at least partially radially expand (e.g., self-expand) when the clot treatment device 130 is no longer constrained by the outer elongate member 106.

[0064] At block 743, the method 740 can include further radially expanding the clot treatment device 130. For example, the clot treatment device 130 can be radially expanded by actuating the actuator 112 of the handle 110 to drive the inner elongate member 102 proximally relative to the middle elongate member 104 to thereby move the distal end portion 131a of the clot treatment device 130 toward the proximal end portion 131b—thereby causing the struts 133 to flex radially outwardly away from the longitudinal axis L. In some embodiments, the clot treatment device 130 is radially expanded outwardly to contact the clot material adhered to the implant or the implant itself. In some aspects of the present technology, such radial expansion can comprise a mechanical “ballooning” effect of the clot treatment device 130. For example, the clot treatment device 130 can be expanded within a deformed or compressed stent to balloon open the stent and/or to disrupt clot material, intimal hyperplasia, and/or other material within the stent such that clot treatment device 130 can more effectively engage and disrupt clot material within the stent (block 744). In some embodiments, the clot treatment device 130 can be expanded within a bare vessel (e.g., outside a stent) to perform angioplasty. The clot treatment device 130 can provide a radial outward mechanical force (e.g., pressure) of between about 0.1–30 atmospheres, between about 0.1–6 atmospheres, etc. The outward mechanical force can be determined by the width and thickness of the struts 133 and/or the amount the clot treatment device 130 can be expanded (e.g., how far the leadscrew 520 can travel)—with greater strut thickness, strut width, and/or device expansion causing a greater outward mechanical force (and vice versa) In some aspects of the present technology, the clot treatment device advantageously does not include a burst failure mode like many conventional balloon treatment devices.

[0065] At block 744, the method 740 includes mechanically engaging the clot treatment device 130 with the clot material within the implant to at least partially dislodge the clot material. For example, the clot treatment device 130 can be rotated, translated, and/or radially compressed/expanded within the implant to engage and dislodge the clot material. Accordingly, in some aspects of the present technology the clot treatment device 130 can function similarly to a mechanical scoring balloon. More specifically, Figure 8 is a distally-facing perspective view of a distal portion of the system 100 including the clot treatment device 130 expanded within an implant 850 (e.g., a stent) implanted in a vessel V in accordance with embodiments of

the present technology. The clot material to be removed is omitted in Figure 8 for clarity. The implant 850 can comprise a plurality of interconnected struts, graft material, a mesh, and/or other components known in the art of intravascularly implantable medical devices (e.g., stents).

[0066] In the illustrated embodiment, the clot treatment device 130 is expanded within a lumen 852 of the implant 850 such that the struts 133 contact an inner surface of the implant 850. In some embodiments, the struts 133 are the only part of the clot treatment device 130 that contacts the implant 850 when the clot treatment device 130 is expanded. With reference to Figures 1A and 8 together, the clot treatment device 130 can be (i) translated distally or proximally within the implant 850 (e.g., as indicated by arrow A in Figure 8) by moving the handle 110 distally or proximally and/or (ii) rotated clockwise or counterclockwise within the implant 850 (e.g., as indicated by arrows C and CC, respectively, in Figure 8) by rotating the handle 110. As described in detail above, the elongate members 102, 104 can be formed to be highly torqueable and to have high compression/tension resistance such that the movements of the handle 110 are translated without much loss to the clot treatment device 130. In some aspects of the present technology, the struts 133 are configured not to catch, grab, or damage the implant 850 when the clot treatment device 130 is moved relative to the implant 850 as, for example, the struts 133 extend generally axially along the direction of translation and do not include any cross-members or open cells. Additionally, the undulating shapes of the struts 133 (e.g., the circumferential portions 137) together define an abrasive surface for disrupting, cutting, and/or dislodging the clot material adhered to the implant 850. Accordingly, in some aspects of the present technology the system 100 can be used to remove chronic adherent clot while significantly reducing the risk of damaging the implant 850.

[0067] Referring again to Figure 7, at block 745, the method 740 optionally includes collapsing and repositioning the clot treatment device 130. For example, if the clot treatment device 130 catches or becomes entangled with the implant, the clot treatment device 130 can be radially compressed (e.g., from the first position to the second position shown in Figures 6A and 6B, respectively) to disengage the implant. For example, Figures 9A and 9B are distally-facing perspective views of a distal portion of the system 100 including the clot treatment device 130 positioned within the implant 850 in the vessel V in accordance with embodiments of the present technology. Figure 9A illustrates the clot treatment device 130 in a radially-expanded position and at least partially entangled with an end portion 954 of the implant 850. If such entanglement occurs, the clot treatment device 130 can be radially compressed as shown in Figure 9B to free the struts 133 from the implant 850. In some aspects of the present technology, because the clot

treatment device 130 does not include any cross-members between the struts 133, radially compressing the clot treatment device 130 can disengage the struts 133 from the implant 850 without catching or pulling the implant 850 therewith.

[0068] Referring again to Figure 7, at block 746, the method 740 can include at least partially capturing the dislodged clot material within, for example, the outer elongate member 106. In some embodiments, the clot material dislodged from the implant (block 744) can flow into the outer elongate member 106 via the blood pressure within the vessel. In some embodiments, the clot treatment device 130 can be retracted proximally into the outer elongate member 106 to pull the clot material into the outer elongate member 106.

[0069] Finally, at block 747, the system 100 can be withdrawn from the patient. For example, the clot treatment device 130 can be retracted proximally into the outer elongate member 106 (e.g., by proximally withdrawing the handle 110 relative to the outer elongate member 106) and radially constrained therein. The outer elongate member 106 and the constrained clot treatment device 130 can then be withdrawn together from the patient.

[0070] Figures 10A–10C are distally-facing perspective views of a distal portion of the system 100 including the clot treatment device 130 expanded within an implant 1050 with differing amounts of radial expansion in accordance with embodiments of the present technology. More specifically, Figures 10A–10C illustrate progressively increasing amounts of radial expansion caused by for, example, further actuation of the actuator 112 of the handle 110 to move the distal end portion 131a of the clot treatment device 130 proximally toward proximal end portion 131b of the clot treatment device as shown in and described in detail with reference to Figures 1A–6B. Alternatively, Figures 10A–10C illustrate the same amount of radial expansion of the clot treatment device 130 where the implant 1050 has a progressively decreasing diameter E_1 – E_3 .

[0071] Referring to Figures 10A–10C together, as the clot treatment device 130 is further expanded within the implant 1050, the struts 133 can progressively flex inward and turn to each have a scoop-like shape. More specifically, the distal and proximal portions 134, 136 of each strut can flex to be circumferentially offset relative to the longitudinal axis L (Figure 1B) of the clot treatment device 130. Such radial offset can be facilitated by the different properties of the elongate members 104, 106. For example, as described in detail above, the inner elongate member 102 can comprise a solid tube while the middle elongate member 104 can comprise a hollow helical spiral such that there is more rotational give in the middle elongate member 104.

Accordingly, when the clot treatment device 130 is rotated when it is engaged with a stent or other implant, the friction/engagement forces on the clot treatment device 130 can cause the relatively more flexible middle elongate member 104 to rotate less than the inner elongate member 102—thereby rotating the distal end portion 131a (Figures 6A and 6B) of the clot treatment device 130 more than the proximal end portion 131b (Figures 6A and 6B) and causing the scoop-like shape. In some aspects of the present technology, the scoop-like shape of the struts 133 shown in Figures 10B and 10C can facilitate a more effective removal of clot material from implant 1050. In other embodiments, the elongate members 104, 106 can be coupled to a handle configured to rotate the elongate members 104, 106 at different speeds to circumferentially offset the distal and proximal end portions of the struts 133 to thereby facilitate the scoop-like shape.

[0072] Figure 11A is a side view of a stent cleaning system 1100 (“system 1100”) in accordance with embodiments of the present technology. The system 1100 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the system 1100 described in detail above with reference to Figures 1A–10C, and can operate in a generally similar or identical manner to the system 100. For example, in the illustrated embodiment, the system 1100 includes a clot treatment device 1130 having a distal end portion 1131a coupled to the inner elongate member 102 and a proximal end portion 1131b coupled to the middle elongate member 104. The elongate members 102, 104 extend through the outer elongate member 106 and are operably coupled to a handle 1110 configured to radially expand/compress the clot treatment device 1130. In some embodiments, the system 1100 is configured for use in the peripheral vasculature to treat chronic peripheral clot either within a stent or other implant, or within a bare vessel.

[0073] Figures 11B and 11C are side views of a distal portion of the system 1100 including the clot treatment device 1130 in a first position (e.g., a radially-expanded position) and a second position (e.g., a radially-compressed position), respectively, in accordance with embodiments of the present technology. In the illustrated embodiment, the clot treatment device 1130 includes a plurality of interconnected struts 1133 that extend between the distal and proximal end portions 1131a-b. In some embodiments, the struts 1133 define a plurality of proximal cells 1160 and a plurality of distal cells 1162. In the illustrated embodiment, the proximal cells 1160 are larger than the distal cells 1162. That is, the clot treatment device 1130 can have fewer of the struts 1133 near the proximal end portion 1131b than near the distal end portion 1131a. The clot treatment device 1130 can be formed of a self-expanding material, such as nitinol, and can be a

unitary/integral structure. In some embodiments, the clot treatment device 1130 can be at least generally similar in structure and function, or identical in structure and function, to any of the clot treatment devices disclosed in U.S. Patent Application No. 17/072,909, titled “SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS,” and filed October 16, 2020, which is incorporated herein by reference in its entirety.

[0074] Referring again to Figure 11A, the handle 1110 can include a first actuator 1112 coupled to one of the elongate members 102, 104 (e.g., the inner elongate member 102). The other one of the elongate members 102, 104 (e.g., the middle elongate member 104) can be fixedly coupled to the handle 1110. In the illustrated embodiment, the first actuator 1112 is a pull member configured to be pulled proximally or advanced distally to move the elongate members 102, 104 relative to one another to radially compress or expand the clot treatment device 1130. In some embodiments, the handle 1110 further includes a second actuator 1119 operably coupled to both of the elongate members 102, 104 and configured to be rotated to rotate the elongate members 102, 104 together to rotate the clot treatment device 1130.

[0075] Referring to Figures 11A–11C together, in operation, the handle 1110 can be advanced distally and withdrawn proximally relative to the outer elongate member 106 to advance the clot treatment device 1130 from within the outer elongate member 106 and/or to withdraw the clot treatment device 1130 into the outer elongate member 106. When the clot treatment device 1130 is advanced out of the outer elongate member 106, the clot treatment device 1130 can self-expand within, for example, a stent or other implant to be cleaned. The first actuator 1112 can be pulled/withdrawn to move the clot treatment device 1130 between the first and second positions shown in Figures 11B and 11C. For example, when the first actuator 1112 is coupled to the inner elongate member 102, the first actuator 1112 can be advanced distally to drive the inner elongate member 102 distally relative to the middle elongate member 104 to drive the distal end portion 1131a of the clot treatment device 1130 distally relative to the proximal end portion 1131b to compress the clot treatment device 1130 (e.g., to move the clot treatment device 1130 from the first position to the second position). Likewise, the first actuator 1112 can be retracted proximally to drive the inner elongate member 102 proximally relative to the middle elongate member 104 to drive the distal end portion 1131a of the clot treatment device 1130 proximally relative to the proximal end portion 1131b to expand the clot treatment device 1130 (e.g., to move the clot treatment device 1130 from the second position to the first position). The second actuator 1119 can be rotated to rotate elongate members 102, 104 together to rotate the clot treatment device 1130 in either the first or second positions. Accordingly, when

expanded within a stent or other implant, the system 1100 is operable to radially expand, translate, and/or rotate the clot treatment device 1130 within the stent to mechanically engage and dislodge clot or other material adhered thereto.

[0076] Figure 12 is a side view of a clot treatment device 1230 in accordance with embodiments of the present technology. The clot treatment device 1230 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130 and/or 1130 described in detail above with reference to Figures 1A–11C, and can be employed within a clot treatment system (e.g., the systems 100 or 110) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

[0077] In the illustrated embodiment, the clot treatment device 1230 includes a plurality of interconnected struts extending between a distal end portion 1231a and a proximal end portion 1231b. More specifically, the clot treatment device 1230 can include (i) distal struts 1264 that extend from the distal end portion 1231a generally axially relative to a longitudinal axis L of the clot treatment device 1230, (ii) proximal struts 1266 that extend from the proximal end portion 1231b generally axially relative to the longitudinal axis L of the clot treatment device 1230, and (iii) bracing struts 1265 connecting the distal struts 1264 to the proximal struts 1266. The bracing struts 1265 can extend at least partially circumferentially relative to the longitudinal axis L in a middle region of the clot treatment device 1230 and can have a chevron- or ring-like pattern. In some aspects of the present technology, the bracing struts 1265 can facilitate an increased torque response of the clot treatment device 1230, while the distal and proximal struts 1264, 1266 extend generally axially to allow the clot treatment device 1230 to be advanced and retracted through an implanted stent without catching on the stent, which could potentially damage or move the stent.

[0078] Figure 13 is a side view of a clot treatment device 1330 in accordance with embodiments of the present technology. The clot treatment device 1330 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, and/or 1230 described in detail above with reference to Figures 1A–12, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

[0079] In the illustrated embodiment, the clot treatment device 1330 includes a plurality of interconnected struts extending between a distal end portion 1331a and a proximal end portion 1331b. More specifically, the clot treatment device 1330 can include (i) distal struts 1364 extending from the distal end portion 1331a, (ii) proximal struts 1366 extending from the proximal end portion 1331b, and (iii) middle struts 1365 (e.g., spanning struts, axial struts) extending between the distal and proximal struts 1364, 1366. In some embodiments, the clot treatment device 1330 includes fewer of the middle struts 1365 than the distal and proximal struts 1364, 1366, and the middle struts 1365 can be longer than the distal and proximal struts 1364, 1366. In the illustrated embodiment, the middle struts 1365 extend in a spiral or helical pattern relative to a longitudinal axis L of the clot treatment device 1330. The distal and proximal struts 1364, 1366 can have a chevron- or ring-like pattern. In some aspects of the present technology, the spiral shape of middle struts 1365 can facilitate an increased torque response of the clot treatment device 1330 while also reducing engagement of the clot treatment device 1330 with an implanted stent. In some embodiments, the clot treatment device 1330 can be rotated such that the middle struts 1365 turn away from the ends of an implanted stent (e.g., by rotating the distal and proximal end portions 1331a-b in opposite directions) to further reduce stent engagement.

[0080] Figure 14 is a side view of a clot treatment device 1430 in accordance with embodiments of the present technology. The clot treatment device 1430 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, and/or 1330 described in detail above with reference to Figures 1A–13, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

[0081] In the illustrated embodiment, the clot treatment device 1430 includes a plurality of interconnected struts extending between a distal end portion 1431a and a proximal end portion 1431b. More specifically, the clot treatment device 1430 can include (i) distal struts 1464 extending from the distal end portion 1431a, (ii) proximal struts 1466 extending from the proximal end portion 1431b, and (iii) middle struts 1465 (e.g., spanning struts, axial struts) extending between the distal and proximal struts 1464, 1466 and generally axially relative to a longitudinal axis L of the clot treatment device 1430. In some embodiments, the clot treatment device 1430 includes fewer of the middle struts 1465 than the distal and proximal struts 1464, 1466, and the middle struts 1465 can be longer than the distal and proximal struts 1464, 1466.

In some aspects of the present technology, the distal and proximal struts 1464, 1466 can facilitate an increased torque response of the clot treatment device 1430, while the axially-extending middle struts 1465 reduce engagement of the clot treatment device 1430 with an implanted stent. In some embodiments, the clot treatment device 1430 further includes bumps 1467 (e.g., radially-extending portions) on the middle struts 1465 configured to increase the radial force of the clot treatment device 1430 for, for example, engaging and dislodging the most adhered clot or other material within the implanted stent.

[0082] Figure 15 is a side view of a clot treatment device 1570 in accordance with embodiments of the present technology. The clot treatment device 1570 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, 1330, and/or 1430 described in detail above with reference to Figures 1A–14, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

[0083] In the illustrated embodiment, the clot treatment device 1570 includes an inner clot treatment device 1530 and an outer clot treatment device 1572 (e.g., a stent protection element) that houses the inner clot treatment device 1530. The inner clot treatment device 1530 can be identical to any of the clot treatment devices 130, 1130, 1230, 1330, and/or 1430 described in detail above with reference to Figures 1A–14 and, in the illustrated embodiment, is identical to the clot treatment devices 1330 of Figure 13. In the illustrated embodiment, the outer clot treatment device 1572 includes a distal end portion 1571a, a proximal end portion 1571b, and a plurality of struts 1573 extending (e.g., axially) between the distal and proximal end portions 1571a-b. The proximal end portion 1571b can be coupled to an elongate member 1574, and the inner clot treatment device 1530 can be advanceable through a lumen of the elongate member 1574 or fixed relative to the elongate member 1574. In some embodiments, the outer clot treatment device 1572 is configured to be radially expanded and/or compressed via movement of the inner clot treatment device 1530. For example, the outer clot treatment device 1572 can be formed of nitinol or another relatively flexible material such that expansion (e.g., via any of the handles described above) of the inner clot treatment device 1530 also expands the outer clot treatment device 1572.

[0084] During a clot treatment procedure, the outer clot treatment device 1572 can directly engage an implanted stent while the inner clot treatment device 1530 is rotated therein and/or while the clot treatment device 1570 is translated distally and/or proximally within the implanted stent. Moreover, the outer clot treatment device 1572 can be fixed so that it does not rotate with the inner clot treatment device 1530 via its connection to the elongate member 1574. In some aspects of the present technology, the outer clot treatment device 1572 can partially or fully protect the implanted stent from being directly contacted by the inner clot treatment device 1530—thereby reducing stent engagement that might damage or disrupt the stent. Further, the outer clot treatment device 1572 can still provide a large inner diameter that allows the inner clot treatment device 1530 to engage and disrupt clot or other material adhered to the stent.

[0085] Figures 16A–16C are side views of a clot treatment device 1630 in accordance with embodiments of the present technology. The clot treatment device 1630 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment devices 130, 1130, 1230, 1330, 1430, and/or 1530 described in detail above with reference to Figures 1A–15, and can be employed within a clot treatment system (e.g., the systems 100 or 1100) in a generally similar or identical manner to mechanically engage and dislodge clot material within an implanted stent or other implant.

[0086] Referring to Figures 16A–16C together, the clot treatment device 1630 includes a plurality of struts 1633 extending between a distal end portion 1631a and a proximal end portion 1631b. Referring to Figure 16A, the clot treatment device 1630 can include a distal clot collection member 1678. The clot collection member 1678 can comprise a plurality of dense cells formed by the struts 1633, or a separate member attached to the struts 1633, such as a bag (e.g., a mesh bag, a short nitinol bag, and/or the like). In some aspects of the present technology, the clot collection member 1678 can capture clot material as the clot treatment device 1630 is moved (e.g., translated, rotated) within an implanted stent. Referring to Figure 16B, in some embodiments the clot treatment device 1630 can further include an expandable member 1679, such as a balloon, positioned radially within the struts 1633. The expandable member 1679 can be expanded to force the struts 1633 radially outward to, for example, provide additional support for dislodging adherent clot material from an implanted stent. In the illustrated embodiment, the expandable member 1679 is positioned only within a proximal portion of the clot treatment device 1630. In other embodiments, the expandable member 1679 can be positioned along the entire length of the clot treatment device 1630, or in a different portion of the clot treatment

device 1630 (e.g., a distal portion). For example, as shown in Figure 16C, the expandable member 1679 is positioned along an entire length of the clot treatment device 1630. Moreover, in the illustrated embodiment the clot collection member 1678 is omitted.

[0087] Figures 17A and 17B are side views of a distal portion of a stent cleaning system 1700 (“system 1700”) in accordance with embodiments of the present technology. Referring to Figures 17A and 17B together, the system 1700 includes an elongate member 1706 and a clot treatment device 1780 advanceable through the elongate member 1706. The clot treatment device 1780 includes a pair of expandable arms 1782 that can be formed of nitinol or similar materials. In Figure 17A, the clot treatment device 1780 is constrained within the elongate member 1706 such that the arms 1782 extend generally linearly through the lumen of the elongate member 1706. Figure 17B illustrates the clot treatment device 1780 after advancement of the clot treatment device 1780 from the elongate member 1706. In the illustrated embodiment, the arms 1782 are configured to expand radially and curve back proximally (e.g., each forming a U-like shape) when unconstrained by the elongate member 1706. The clot treatment device 1780 can be deployed within an implanted stent and rotated to engage and dislodge (e.g., cut) clot or other material adhered to the stent. In some embodiments, the arms 1782 can each have a tapered end portion 1784 configured to inhibit the arms 1782 from interacting with or damaging the stent.

[0088] In any of the embodiments described above with reference to Figures 1A–17B, a clot treatment device can include struts with a chamfer or angle to improve the ability of the clot treatment device to cut through adhered clot surfaces. At the same time, such a chamfer can allow the struts to be made relatively thick to increase their radial force. More specifically, for example, Figure 18 illustrates several struts having different chamfers that can be used in a clot treatment device in accordance with embodiments of the present technology. Figure 19 is an enlarged side view of a pair of struts 1933 of a clot treatment device each having a chamfered edge 1986 in accordance with embodiments of the present technology.

[0089] In other embodiments, a handle in accordance with the present technology can have other configurations for (i) driving a pair of elongate members (e.g., the elongate members 102, 104 of Figures 1A–1C) relative to one another to radially expand/compress a clot treatment device (e.g., the clot treatment device 130) and/or (ii) rotating the clot treatment device. Figures 21–27, for example, illustrate handles and/or handle components in accordance with embodiments of the present technology that can be incorporated into the system 100, the system

1100, and/or another suitable system instead of or in addition to the handle 110 and/or the handle 1110. The various handles can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of one another, the handle 110 described in detail above with reference to Figures 1A–C and 5, and/or the handle 1110 described in detail above with reference to Figures 11A–11C, and can operate in a generally similar or identical manner to one another, the handle 110, and/or the handle 1110. Moreover, although frequently described in the context of manipulating the clot treatment device 130 shown in Figures 1A–1C, the handles of the present technology can be used to manipulate/control any of the clot treatment devices of the present technology.

[0090] Figure 20, for example, is a side cross-sectional view of a handle 2010 in accordance with embodiments of the present technology that can be incorporated into (e.g., used in) the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2010 includes a housing 2014 and a leadscrew 2020 movably positioned within the housing 2014 and constrained by/over one or more guiderails 2022 (e.g., a pair of the guiderails 2022). The leadscrew 2020 can have a threaded outer surface configured to mate with a threaded inner surface of an actuator 2012, which extends out of the housing 2014 such that the actuator 2012 is accessible outside the housing 2014 by a user of the handle 2010 (e.g., a physician). The inner elongate member 102 can be fixed to the leadscrew 2020, and the middle elongate member 104 (not shown) can be fixed to the housing 2014. Accordingly, actuation (e.g., rotation) of the actuator 2012 can drive the leadscrew 2020 proximally/distally through the housing 2014 to drive the inner elongate member 102 relative to the middle elongate member 104 to radially compress/expand the clot treatment device 130 as shown in Figures 6A and 6B.

[0091] In the illustrated embodiment, the handle 2010 further includes a lock mechanism 2024 coupled to the housing 2014. The lock mechanism 2024 can include a lock member 2025 configured to engage the leadscrew 2020 and/or the actuator 2012 to inhibit movement of the leadscrew 2020 through the housing 2014. In the illustrated embodiment, the lock mechanism 2024 is in a locked position in which the lock member 2025 engages the actuator 2012 to inhibit movement of the actuator 2012 and the leadscrew 2020. In some embodiments, the user can actuate (e.g., push, translate, rotate, depress) the lock mechanism 2024 to withdraw the lock member 2025 away from the actuator 2012 to allow the leadscrew 2020 to move through the housing 2014. Accordingly, with additional reference to Figures 6A and 6B, the user can selectively engage the lock mechanism 2024 to lock the clot treatment device 130 in the first position, the second position, or and/or another position.

[0092] Figure 21 is a side cross-sectional view of a handle 2110 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2110 includes a housing 2114 containing a working fluid 2180. A fluid port 2182 is coupled to the housing 2114 and configured to remove/insert the working fluid 2180 into the housing 2114 via a fluid control system (not shown). The inner elongate member 102 can be coupled to a flange 2181 positioned within the housing 2114 and configured to sealingly engage the housing 2114 such that the working fluid 2180 is positioned only between the flange 2181 and the fluid port 2182. Accordingly, in operation, the working fluid 2180 can be pumped into/out of the housing 2114 to drive the flange 2181 distally/proximally through the housing 2114 to drive the inner elongate member 102 relative to the middle elongate member 104 to radially expand/compress the clot treatment device 130 as shown in Figures 3A and 3B. Therefore, in some aspects of the present technology the handle 2110 can be a pneumatically and/or hydraulically operated handle.

[0093] Figure 22 is an isometric view of an actuation mechanism 2290 of a handle that can be incorporated into the system 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the actuation mechanism 2290 includes an actuator 2212 that is operably coupled to a housing or other component of the handle (not shown) via one or more biasing members 2291, such as coil springs. The actuator 2212 can be operably coupled to (e.g., integrally formed with) a gear rack 2292 having a plurality of teeth configured to engage a first gear 2293 mounted on a first shaft 2294. A second gear 2295 can be mounted on the first shaft 2294, coupled to the first gear 2293, and configured to engage a third gear 2297 mounted on a second shaft 2296. In some embodiments, the second gear 2295 is larger than the first gear 2293. In the illustrated embodiment, the second shaft 2296 is coupled to a unidirectional ratchet mechanism 2298 including, for example, a tooth 2286 that interfaces with circumferentially disposed indents 2288 to allow only counterclockwise rotation.

[0094] Accordingly, in operation, a user can press the actuator 2212 linearly against the biasing force of the biasing members 2291 to drive the gear rack 2292 linearly relative to the first gear 2293. The movement of the gear rack 2292 rotates the first gear 2293 via the engagement of the gear rack 2292 and the first gear 2293. The rotation of the first gear 2293 rotates the coupled second gear 2295, which in turn rotates the third gear 2297 via the engagement of the second and third gears 2295, 2297. In some embodiments, the larger size of the second gear 2295 steps up the rotation speed of the first gear 2293. In some embodiments, the second gear 2295 can be omitted and the first gear 2293 can directly engage the third

gear 2297 or the first shaft 2294 can directly engage the ratchet mechanism 2298. The ratchet mechanism 2298 inhibits or even prevents the third gear 2297 from rotating in multiple directions, such as when the biasing members 2291 return the actuator 2212 to an initial position after being depressed. Accordingly, the actuation mechanism 2290 translates the linear motion of the actuator 2212 to unidirectional rotation of the ratchet mechanism 2298 and the third gear 2297. The ratchet mechanism 2298 and/or the third gear 2297 can be coupled directly to one or both of the elongate members 102, 104 (Figures 1A–1C) such that the actuation mechanism 2290 is configured to rotate the elongate members 102, 104, or the ratchet mechanism 2298 and/or the third gear 2297 can be coupled to a leadscrew or other device such that the actuation mechanism 2290 is configured to drive the elongate members 102, 104 relative to one another to radially expand/compress the clot treatment device 130 as shown in Figures 3A and 3B, as described in detail above.

[0095] In some embodiments, a handle coupled to a clot treatment device can include one or more features for inhibiting or even preventing over expansion and/or over torquing of the clot treatment device. Figure 23, for example, is a side view of a handle 2310 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2310 includes a distal handle portion 2370 and a proximal handle portion 2372. The distal handle portion 2370 can be coupled to a leadscrew 2320 that is coupled to one of the elongate members 102, 104 (e.g., the inner elongate member 102). In the illustrated embodiment, the distal handle portion 2370 is coupled to the proximal handle portion 2372 via a plurality of balls 2371, such as spring-loaded ball bearings, positioned in corresponding detents formed between the distal and proximal handle portions 2370, 2372. Accordingly, in operation, rotation of the proximal handle portion 2372 below a predetermined torque level determined by the balls 2371 and associated detents rotates the distal handle portion 2370 and the leadscrew 2320 to advance one of the elongate members 102, 104 (e.g., the inner elongate member 102) relative to the other one of the elongate members 102, 104 and radially compress/expand the attached clot treatment device 130. However, rotation of the proximal handle portion 2372 above the predetermined torque level (e.g., when a user turns the proximal handle portion 2372 too fast and/or continues to torque the proximal handle portion 2372 when the clot treatment device 130 is significantly engaged with an implant) will cause the balls 2371 to slip from the detents such that the proximal handle portion 2372 rotates relative to the distal handle portion 2370 without rotating the distal handle

portion 2370. In this manner, the handle 2310 is configured to maintain a torque level of the clot treatment device 130 and associated force on an implant below a predetermined level.

[0096] In other embodiments, some or all of the balls 2371 and corresponding detents can be replaced with other mechanisms for inhibiting over torquing of the clot treatment device 130. For example, some or all of the balls 2371 can be replaced with pairs of magnets including a first one of the pair coupled to the distal handle portion 2370 and a second one of the pair coupled to the proximal handle portion 2372. The magnets can be selected such that, when the handle 2310 is over torqued, the pairs of magnets disengage (e.g., shear apart) from one another to permit the proximal handle portion 2372 to rotate relative to the distal handle portion 2370 without rotating the distal handle portion 2370.

[0097] Figure 24 is a side view of a handle 2410 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2410 includes a leadscrew 2420 coupled to an intermediary shaft 2474 having a first stop 2475. Rotation of the leadscrew 2420 in a first direction can drive the intermediary shaft 2474 to translate distally, and rotation of the leadscrew 2420 in a second direction can drive the intermediary shaft 2474 to translate proximally. In the illustrated embodiment, the inner elongate member 102 is configured to at least partially telescope within the intermediary shaft 2474 and includes a second stop 2476. A biasing member 2477 (e.g., a coil spring) can extend between the first stop 2475 and the second stop 2476 to couple the inner elongate member 102 to the intermediary shaft 2474. In operation, when the intermediary shaft 2474 is driven proximally via the leadscrew 2420, the biasing member 2477 pulls the inner elongate member 102 proximally to radially expand the clot treatment device 130. However, the proximal movement also forces the biasing member 2477 to elongate—reducing the proximal movement of the inner elongate member 102 compared to, for example, embodiments where the inner elongate member 102 is directly coupled to the leadscrew 2420. Accordingly, in some aspects of the present technology the biasing member 2477 can limit the radial expansion of the clot treatment device 130 to inhibit over expansion that may damage an implant.

[0098] Figures 25A–25C are an enlarged perspective view, an enlarged side view, and an enlarged cross-sectional side view, respectively, of a handle 2510 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). Referring to Figures 25A–25C together, in the illustrated embodiment, the

handle 2510 includes a housing 2514 (shown as partially transparent in Figures 25A and 25B for clarity) defining an internal chamber or lumen 2516 (Figure 25C). The middle elongate member 104 can be fixedly coupled to the housing 2514. The inner elongate member 102 (not shown; Figures 1A–1C) can extend through the lumen of the middle elongate member 104 into the lumen 2516 of the housing 2514. The handle 2510 can further comprise a leadscrew 2520 attached to the inner elongate member 102 and an actuator 2512 (e.g., a rotatable knob). The leadscrew 2520 is movably positioned within the lumen 2516 and can have a threaded outer surface configured to mate with a threaded inner surface of the actuator 2512. The actuator 112 can extend out of the housing 2514 from one or more first openings 2519 therein (e.g., a pair of openings on opposing sides of the housing 2514) such that the actuator 2512 is accessible outside the housing 2514 by a user of the handle 2510 (e.g., a physician). In operation, the actuator 2512 can be rotated relative to the housing 2514 to drive the leadscrew 2520 proximally and/or distally through the housing 2514 to thereby drive the attached inner elongate member 102 to translate relative to the middle elongate member 104 and thereby radially expand/collapse the clot treatment device 130.

[0099] In the illustrated embodiment, the handle 2510 further comprises an indicator 2511 coupled to the leadscrew 2520. The indicator 2511 can be coupled to (e.g., integrally formed with, rotatably mounted to) the leadscrew 2520 and can project into and/or otherwise be visible through one or more second openings 2518 (e.g., slots) in the housing 2514 (e.g., a pair of openings on opposing sides of the housing 2514). The housing 2514 can further include one or more markings 2517 (Figures 25A and 25B) adjacent to one or more of the second openings 2518 that indicate an amount of expansion of the clot treatment device 130 (e.g., a measurement of the radial expansion of the clot treatment device 130, a state of the clot treatment device 130, a position of the clot treatment device 130, and/or the like). For example, when the actuator 2512 is actuated to drive the inner elongate member 102 and expand/collapse the clot treatment device 130, the indicator 2511 can move with the leadscrew 2520 through and/or along the second openings 2518, and the one of the markings 2517 adjacent the indicator 2511 can indicate the amount of expansion (e.g., in millimeters). In some aspects of the present technology, combining the indicator 2511 with the leadscrew 2520 in such a manner allows to indicator 2511 to more accurately indicate the amount of radial expansion of the clot treatment device 130 because additional component attachment and manufacturing steps for forming the indicator are not needed.

[0100] Figure 26 is an enlarged cross-sectional side view of a handle 2610 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2610 includes a housing 2614 defining an internal chamber or lumen 2616. The middle elongate member 104 can be fixedly coupled to the housing 2614. The inner elongate member 102 can extend through the lumen of the middle elongate member 104 into the lumen 2616 of the housing 2614. The handle 2610 can further comprise a leadscrew 2620 attached to the inner elongate member 102 and an actuator 2612 (e.g., a rotatable knob). The leadscrew 2620 is movably positioned within the lumen 2616 and, in the illustrated embodiment, has a threaded inner surface configured to mate with a threaded outer surface of the actuator 2612. That is, the threaded surfaces of the leadscrew 2620 and the actuator 2612 are opposite those shown in Figures 5 and 25A–25C. The actuator 112 can extend out of the housing 2614 such that a user can rotate the actuator 2612 relative to the housing 2614 to drive the leadscrew 2620 to proximally and/or distally through the housing 2614 to thereby drive the attached inner elongate member 102 to move relative to the middle elongate member 104 and radially expand/collapse the clot treatment device 130.

[0101] In the illustrated embodiment, the handle 2610 further comprises an indicator 2611 coupled to the leadscrew 2620 and that is visible through one or more slot/openings in the housing 2614 to provide an indication of an amount of radial expansion of the clot treatment device 130. In some aspects of the present technology, forming the outer surface of the actuator 2612 and the corresponding inner surface of the leadscrew 2620 to be threaded can allow for easier visualization of the indicator 2611, as the actuator 2612 does not block the view of the indicator 2611 and the leadscrew 2620 anywhere along the path of the leadscrew 2620.

[0102] Figure 27 is an enlarged cross-sectional side view of a handle 2710 in accordance with additional embodiments of the present technology that can be incorporated into the system 100 (e.g., instead of the handle 110). In the illustrated embodiment, the handle 2710 includes a housing 2714 defining an internal chamber or lumen 2716. The middle elongate member 104 can be rotatably coupled to the housing 2714 via a first adaptor 2790 (e.g., a mid-adaptor). In some embodiments, the first adaptor 2790 comprises a flange 2791 configured (e.g., shaped, sized, positioned) to be positioned in and rotatably retained within a corresponding circumferential groove or recess 2792 in the housing 2714. The inner elongate member 102 can extend through the lumen of the middle elongate member 104 into the lumen 2716 of the housing 2714. The handle 2710 can further comprise a leadscrew 2720 rotatably coupled to the inner elongate member 102 via a second adaptor 2794 and an actuator 2712 (e.g., a rotatable knob).

In some embodiments, the second adaptor 2794 comprises a flange 2795 configured (e.g., shaped, sized, positioned) to be positioned in and rotatably retained within a corresponding circumferential groove or recess 2796 in the leadscrew 2720. The first adaptor 2790 can be fixedly attached to the middle elongate member 104, and the second adaptor 2794 can be fixedly attached to the inner elongate member 102 such that rotation of the elongate guide members 2784 rotates the elongate members 102, 104 together to rotate the clot treatment device 130 attached thereto. The leadscrew 2720 is movably positioned within the lumen 2716 and, in the illustrated embodiment, has a threaded outer surface configured to mate with a threaded inner surface of the actuator 2712. In operation, the actuator 2712 can be rotated relative to the housing 2714 to drive the leadscrew 2720 proximally and/or distally through the housing 2714 to thereby drive the attached inner elongate member 102 to move relative to the middle elongate member 104 and radially expand/collapse the clot treatment device 130.

[0103] In the illustrated embodiment, the handle 2710 further comprises one or more elongate guide members 2784 (e.g., torque guide pins) coupling the first adaptor 2790 to the second adaptor 2740 and a rotary motor 2782. The rotary motor 2782 can be operably coupled to an actuator 2780 (e.g., a switch, a button), a power source, a controller, and/or the like, and is actuatable to cause the rotary motor 2782 to rotate the elongate guide members 2784 to thereby rotate the first and second adaptors 2790, 2794 to thereby rotate the elongate members 102, 104. Accordingly, the handle 2710 is motorized to rotate the clot treatment device 130 (e.g., via actuation of the actuator 2780 and operation of the rotary motor 2782) while still being manually actuatable by a user (e.g., via actuation of the actuator 2712 and corresponding movement of the leadscrew 2720) to radially expand the clot treatment device 130.

[0104] In some embodiments, the rotary motor 2782 is configured to fully rotate (e.g., 360°) the clot treatment device 130 in one or both of the clockwise and counterclockwise directions. In some embodiments, the rotary motor 2782 is configured to only partially rotate the clot treatment device 130 (e.g., by about 10°–60°) in the clockwise and/or counterclockwise directions. In some embodiments, of the rotary motor 2782 (e.g., a controller operably coupled thereto) and/or other aspects of the present technology described herein may take the form of computer- or machine- or controller-executable instructions, including routines executed by a programmable computer or controller. Those skilled in the relevant art will appreciate that the technology can be practiced on computer/controller systems other than those shown and described below. The technology can be embodied in a special-purpose computer, controller or data processor that is specifically programmed, configured or constructed to perform one or more

of the computer-executable instructions described below. Accordingly, the terms “computer” and “controller” as generally used herein refer to any data processor and can include Internet appliances and hand-held devices (including palm-top computers, wearable computers, cellular or mobile phones, multi-processor systems, processor-based or programmable consumer electronics, network computers, mini computers and the like). Information handled by these computers can be presented at any suitable display medium, including a liquid crystal display (LCD).

[0105] The technology can also be practiced in distributed environments, where tasks or modules are performed by remote processing devices that are linked through a communications network. In a distributed computing environment, program modules or subroutines may be located in local and remote memory storage devices. Aspects of the technology described below may be stored or distributed on computer-readable media, including magnetic or optically readable or removable computer disks, as well as distributed electronically over networks. Data structures and transmissions of data particular to aspects of the technology are also encompassed within the scope of the embodiments of the technology.

[0106] Figure 28 is a side view of a distal portion of a clot removal system 2800 (“system 2800”) positioned within a vessel V to treat clot material C in accordance with embodiments of the present technology. The system 2800 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the system 100 described in detail above with reference to Figures 1A–10C, and can operate in a generally similar or identical manner to the system 100. For example, in the illustrated embodiment, the system 2800 includes the clot treatment device 130, the inner elongate member 102 (obscured in Figure 28), the middle elongate member 104, the outer elongate member 106, and the tip 108.

[0107] In the illustrated embodiment, the system 2800 further includes a first balloon 2870 coupled to the outer elongate member 106 (e.g., coupled to a distal portion thereof) and a second balloon 2872 coupled to an innermost (e.g., fourth) elongate member 2807. The innermost elongate member 2807 can be moved (e.g., advanced and/or retracted) through the lumen in the tip 108 and the inner elongate member 102. The first and second balloons 2870, 2872 can be inflated via one or more components of the handle 110 (Figure 5), a separate handle, and/or a different inflation component to an inflated state shown in Figure 28 in which the balloons at least partially engage the wall of the vessel V. Accordingly, the outer elongate member 106, the

innermost elongate member 2807, and/or other components of the system 2800 can include one or more inflation lumens (not shown) for inflating the first and second balloons 2870, 2872.

[0108] The system 2800 can be used to treat the clot material C when the clot material C is positioned within a bare vessel and/or an implant. The clot material C can be chronic or adherent clot material that may otherwise be difficult to treat and remove. In operation, during a clot removal procedure, the outer elongate member 106 can be positioned proximal to the clot material C such that the first balloon 2870 is positioned proximal to the clot material C within the vessel V. The innermost elongate member 2807 can be positioned such that the second balloon 2872 is distal to the clot material C within the vessel V. The clot treatment devices 130 can be deployed between the first and second balloons 2870, 2872 within the clot material C. With the first and second balloons 2870, 2872 inflated, the clot treatment device 130 can be translated and/or rotated through the clot material C to treat and remove the clot material C as described in detail above with reference to, for example, Figure 7. In some aspects of the present technology, the first and second balloons 2870, 2872 can help stabilize the vessel V—inhibiting or even prohibiting it from moving—when the clot treatment device 130 is moved to treat the clot material C. This can help improve the treatment efficiency of the system 2800. In some embodiments, the first balloon 2870 and/or the second balloon 2872 can provide embolic protection during a clot treatment procedure with the clot treatment device 130 in addition to or alternatively to vessel stabilization.

[0109] Several aspects of the present technology are set forth in the following examples:

1. A system for removing clot material from an implant positioned within a body vessel, comprising:

- a clot treatment device configured to be deployed within the implant, wherein the clot treatment device includes a first end portion, a second end portion, and a plurality of struts extending between the first end portion and the second end portion;
- a handle including an actuator;
- a first elongate member coupling the first end portion of the clot treatment device to the handle; and
- a second elongate member coupling the second end portion of the clot treatment device to the handle, wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance

between the first end portion and the second end portion to radially expand the struts.

2. The system of example 1 wherein the implant is a stent.
3. The system of example 1 or example 2 wherein the first end portion is a proximal end portion of the clot treatment device, and wherein the second end portion is a distal end portion of the clot treatment device.
4. The system of example 3 wherein the second elongate member extends through a lumen of the first elongate member.
5. The system of example 1 or example 2 wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device.
6. The system of any one of examples 1–5 wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle.
7. The system of any one of examples 1–6 wherein the handle is rotatable to rotate the clot treatment device relative to the implant.
8. The system of any one of examples 1–7 wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant.
9. The system of any one of examples 1–8 wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant.
10. The system of any one of examples 1–9, further comprising a guide catheter, wherein the clot treatment device is configured to be (a) covered within the guide catheter in a first state and (b) uncovered from the guide catheter and expanded to a second state.

11. The system of any one of examples 1–10 wherein the struts extend generally axially between the first and second end portions and each have an undulating shape.

12. The system of any one of examples 1–11 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

13. The system of any one of examples 1–12 wherein the actuator is a rotatable knob or a slider.

14. The system of any one of examples 1–13 wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded.

15. A method of removing clot material from an implant positioned within a body vessel, the method comprising:

positioning a clot treatment device at least partially within the implant, wherein the clot treatment device has (a) a first end portion, (b) a second end portion, and (c) a plurality of struts extending between the first end portion and the second end portion;

moving the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts; and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts.

16. The method of example 15 wherein the first end portion of the clot treatment device is coupled to a first elongate member, wherein the second end portion of the clot treatment device is coupled to a second elongate member, and wherein moving the second elongate relative to the first elongate member comprises actuating an actuator on a handle coupled to the first elongate member and the second elongate member to move the second elongate member relative to the first elongate member.

17. The method of example 15 or example 16 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

18. The method of any one of examples 15–17 wherein the implant is a stent.

19. A clot treatment device, compressing:

a proximal end portion;

a distal end portion; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion, wherein—

movement of the first end portion toward the second end portion is configured to radially expand the struts;

individual ones of the struts include a proximal portion extending from the proximal end portion, a distal portion extending from the distal end portion, and a middle portion (a) extending between the proximal portion and the distal portion and (b) having a hook-like shape in a direction about the longitudinal axis; and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis.

20. The clot treatment device of example 19 wherein the clot treatment device does not include any cross-members interconnecting the struts.

[0110] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form 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.

[0111] 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.

[0112] Moreover, unless the word “or” is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of “or” in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. 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 system for removing clot material from an implant positioned within a body vessel, comprising:
 - a clot treatment device configured to be deployed within the implant, wherein the clot treatment device includes a first end portion, a second end portion, and a plurality of struts extending between the first end portion and the second end portion;
 - a handle including an actuator;
 - a first elongate member coupling the first end portion of the clot treatment device to the handle; and
 - a second elongate member coupling the second end portion of the clot treatment device to the handle, wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts.
2. The system of claim 1 wherein the implant is a stent.
3. The system of claim 1 wherein the first end portion is a proximal end portion of the clot treatment device, and wherein the second end portion is a distal end portion of the clot treatment device.
4. The system of claim 3 wherein the second elongate member extends through a lumen of the first elongate member.
5. The system of claim 1 wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device.
6. The system of claim 1 wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle.

7. The system of claim 1 wherein the handle is rotatable to rotate the clot treatment device relative to the implant.

8. The system of claim 1 wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant.

9. The system of claim 1 wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant.

10. The system of claim 1, further comprising a guide catheter, wherein the clot treatment device is configured to be (a) covered within the guide catheter in a first state and (b) uncovered from the guide catheter and expanded to a second state.

11. The system of claim 1 wherein the struts extend generally axially between the first and second end portions and each have an undulating shape.

12. The system of claim 1 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

13. The system of claim 1 wherein the actuator is a rotatable knob or a slider.

14. The system of claim 1 wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded.

15. A method of removing clot material from an implant positioned within a body vessel, the method comprising:

positioning a clot treatment device at least partially within the implant, wherein the clot treatment device has (a) a first end portion, (b) a second end portion, and (c) a plurality of struts extending between the first end portion and the second end portion;

moving the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts; and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts.

16. The method of claim 15 wherein the first end portion of the clot treatment device is coupled to a first elongate member, wherein the second end portion of the clot treatment device is coupled to a second elongate member, and wherein moving the second elongate relative to the first elongate member comprises actuating an actuator on a handle coupled to the first elongate member and the second elongate member to move the second elongate member relative to the first elongate member.

17. The method of claim 15 wherein the struts each extend axially between the first and second end portions, and wherein the clot treatment device does not include any cross-members interconnecting the struts.

18. The method of claim 15 wherein the implant is a stent.

19. A clot treatment device, compressing:

a proximal end portion;

a distal end portion; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion, wherein—

movement of the first end portion toward the second end portion is configured to radially expand the struts;

individual ones of the struts include a proximal portion extending from the proximal end portion, a distal portion extending from the distal end portion, and a middle portion (a) extending between the proximal portion and the distal portion and (b) having a hook-like shape in a direction about the longitudinal axis; and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis.

20. The clot treatment device of claim 19 wherein the clot treatment device does not include any cross-members interconnecting the struts.

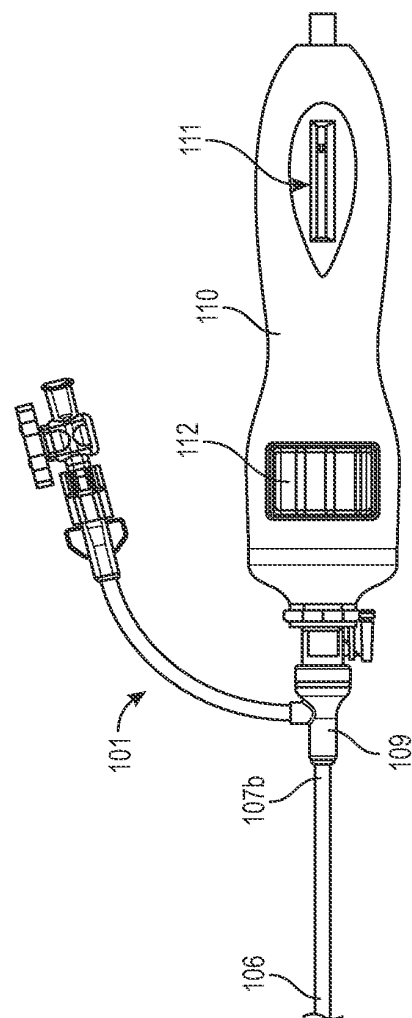


FIG. 1A

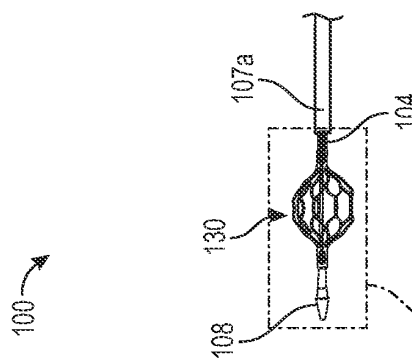


FIG. 1B

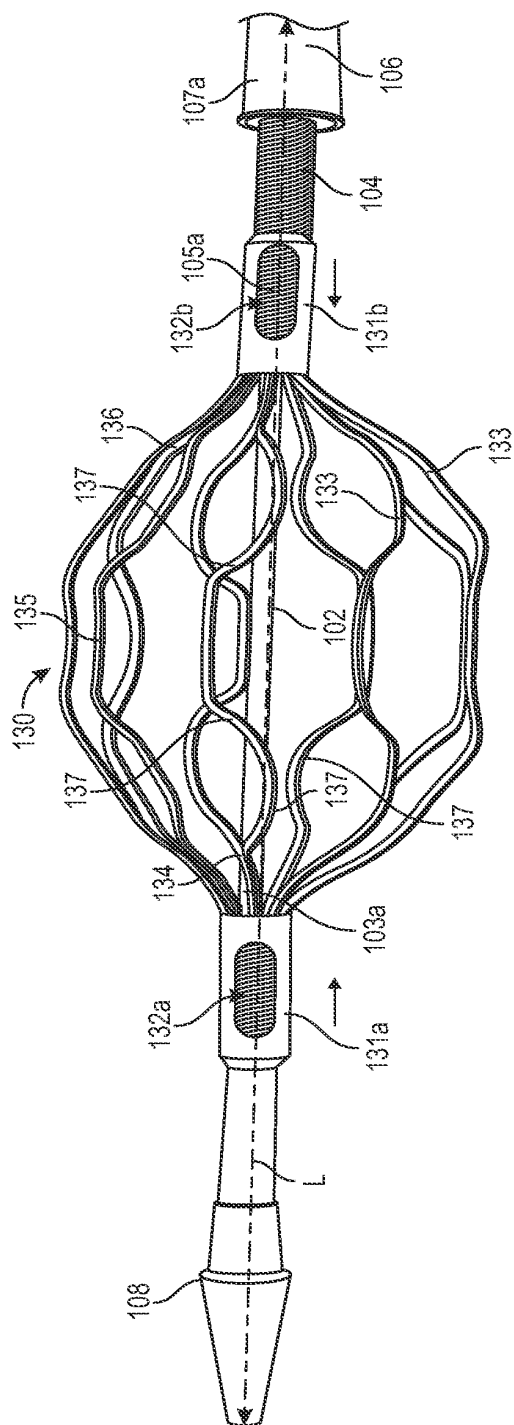


FIG. 1B

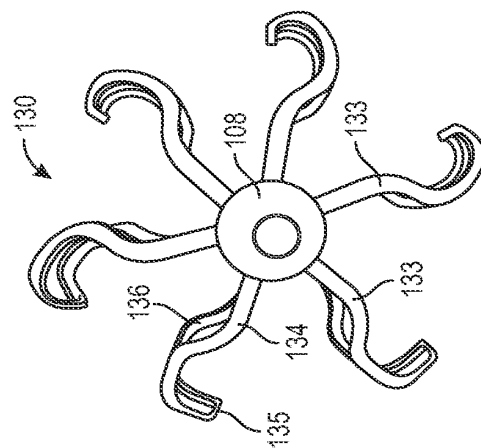


FIG. 1C

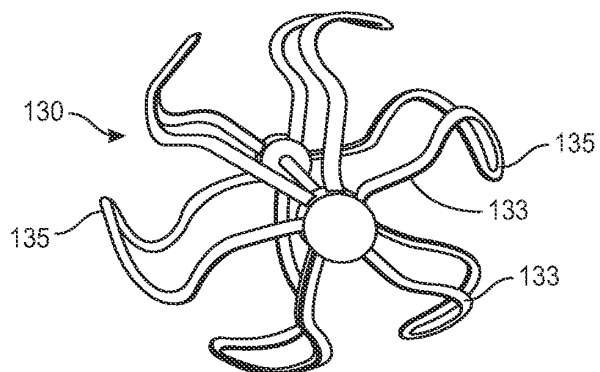


FIG. 2A

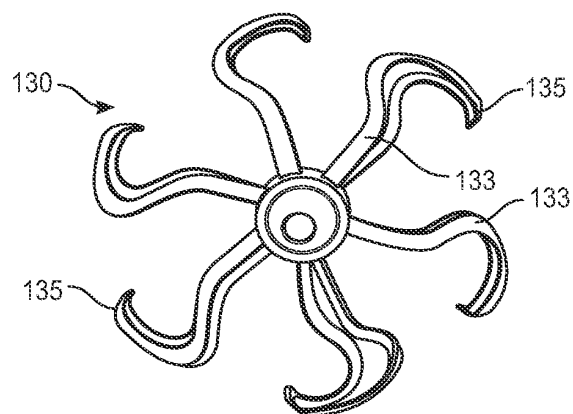


FIG. 2B

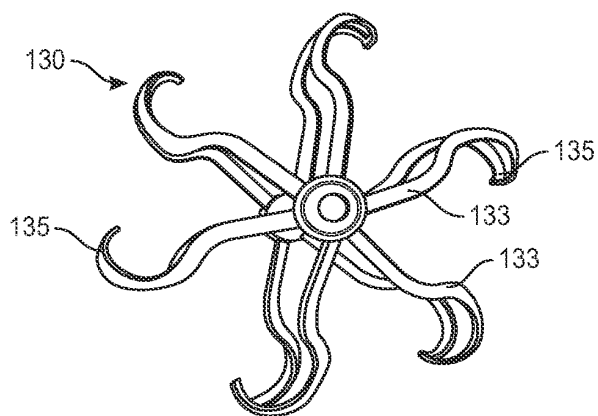


FIG. 2C

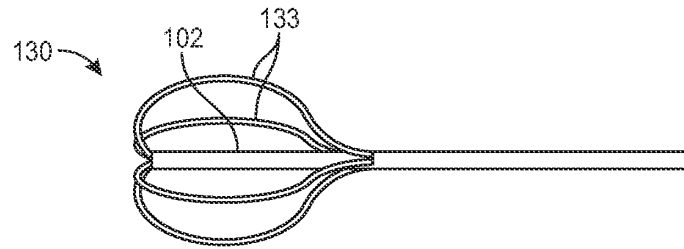


FIG. 3A

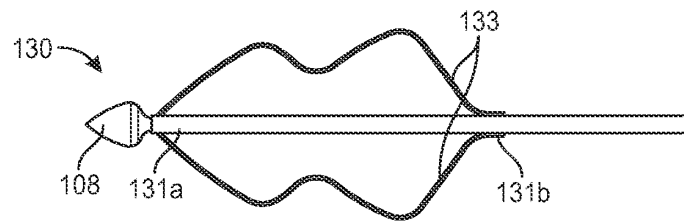


FIG. 3B

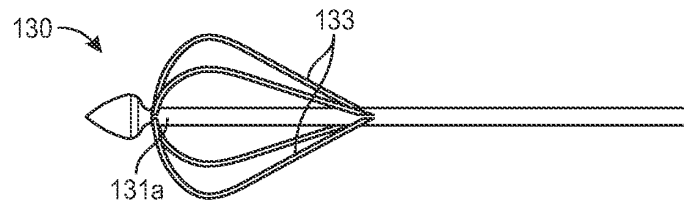


FIG. 3C

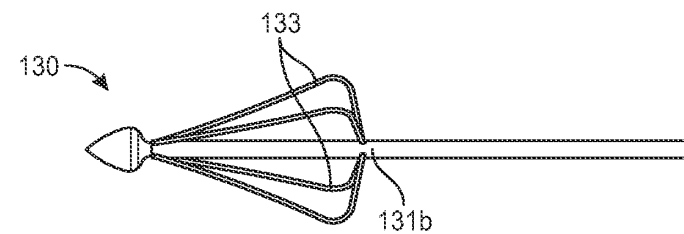


FIG. 3D

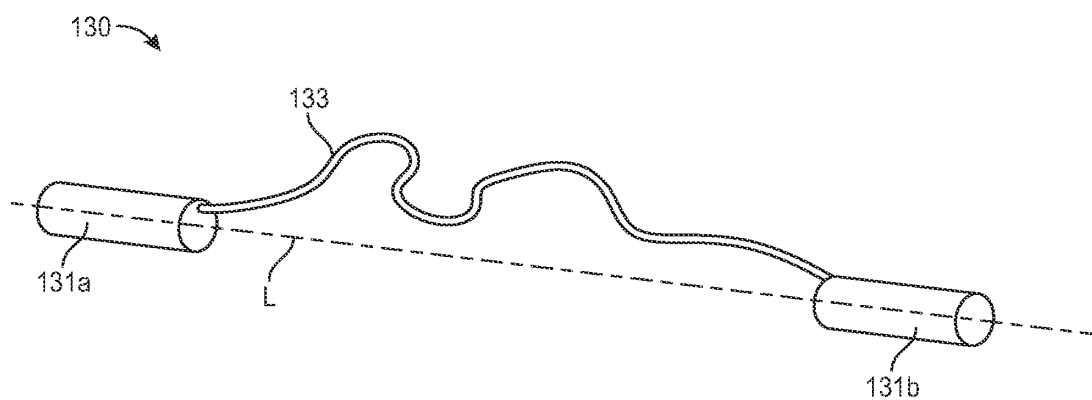


FIG. 4A

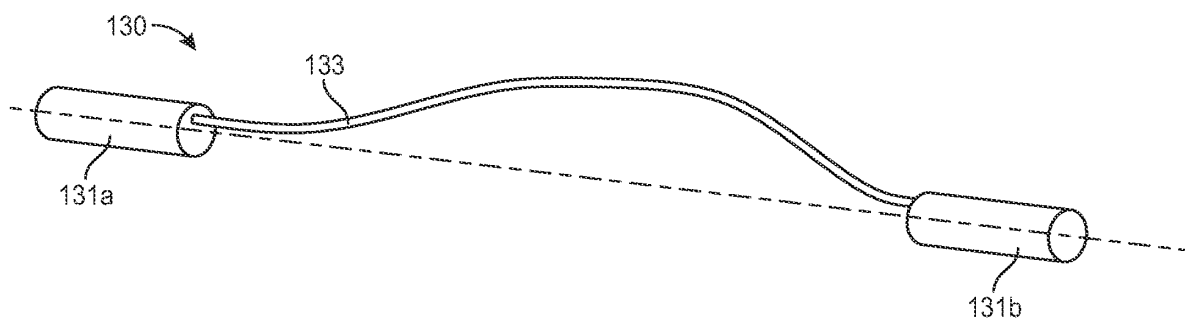


FIG. 4B

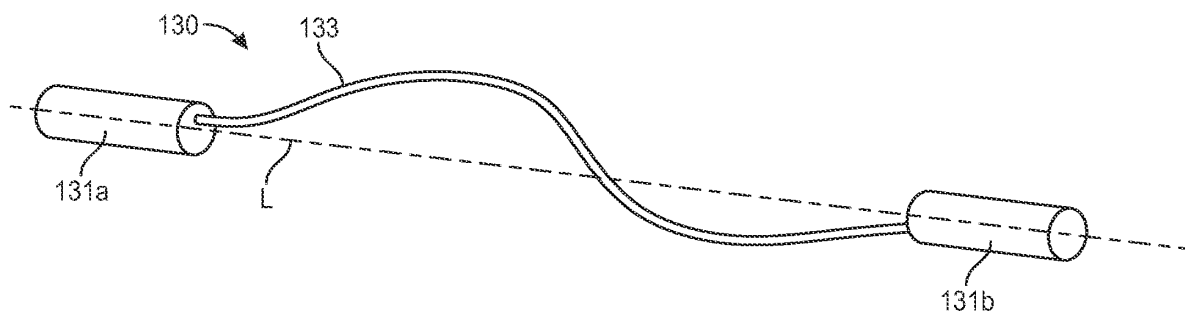


FIG. 4C

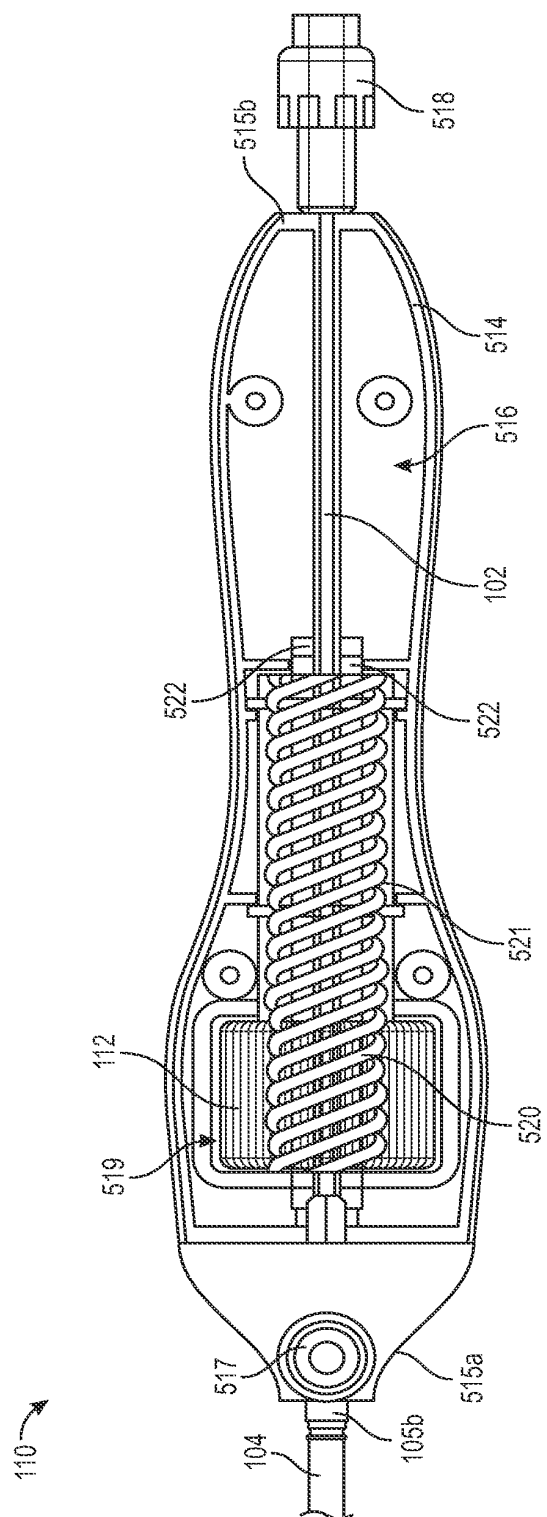


FIG. 5

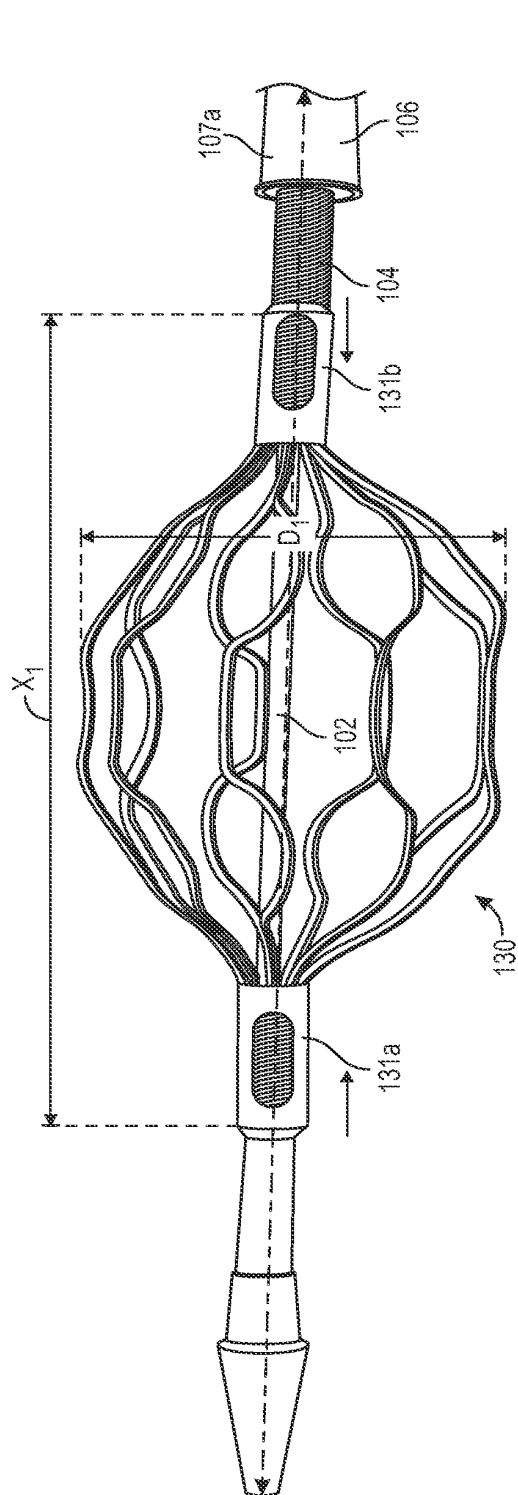


FIG. 6A

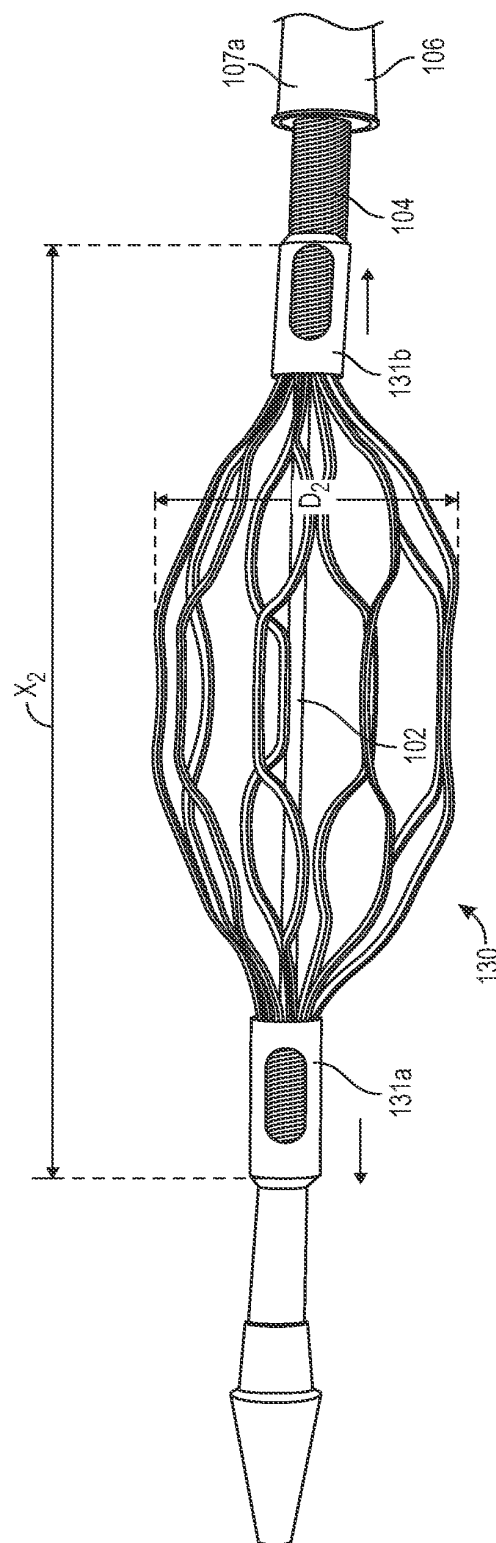
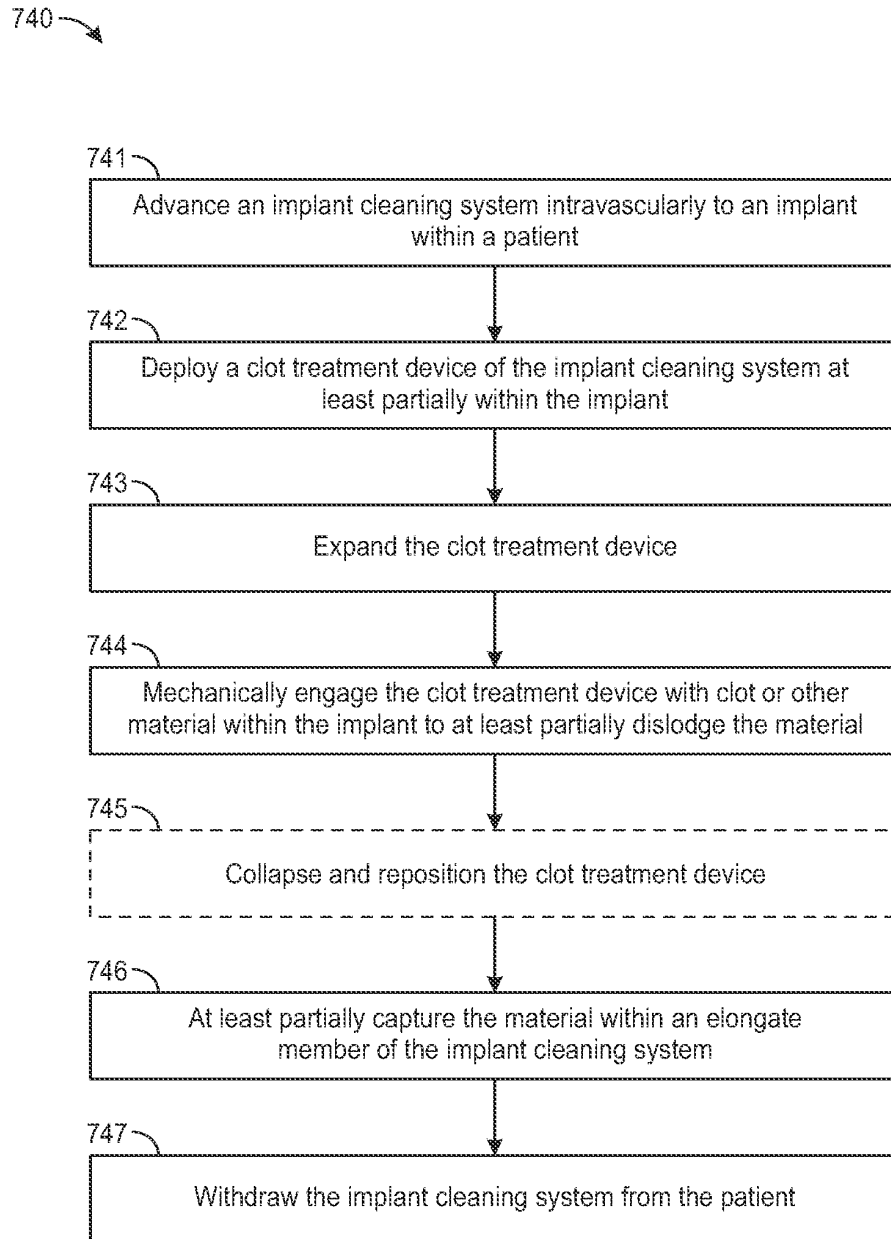


FIG. 6B

**FIG. 7**

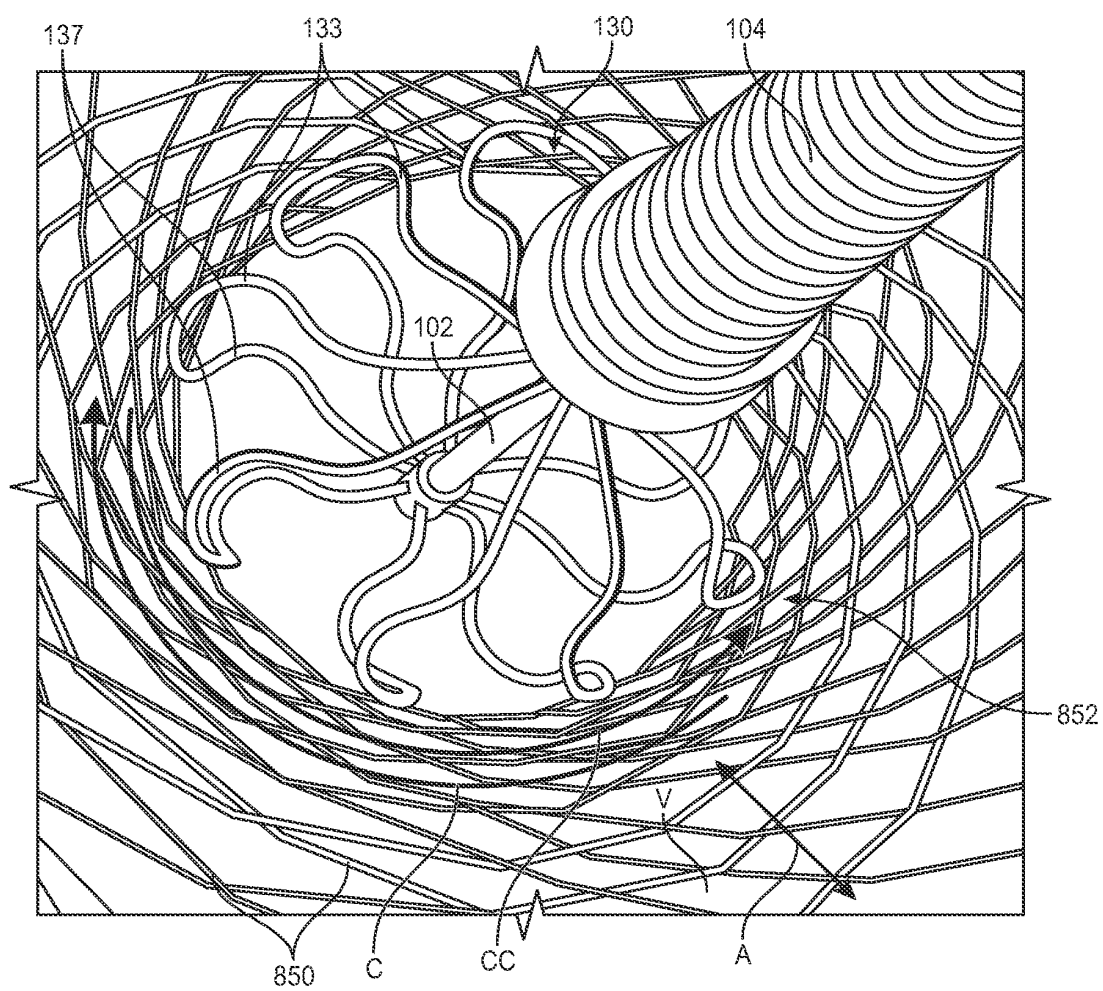


FIG. 8

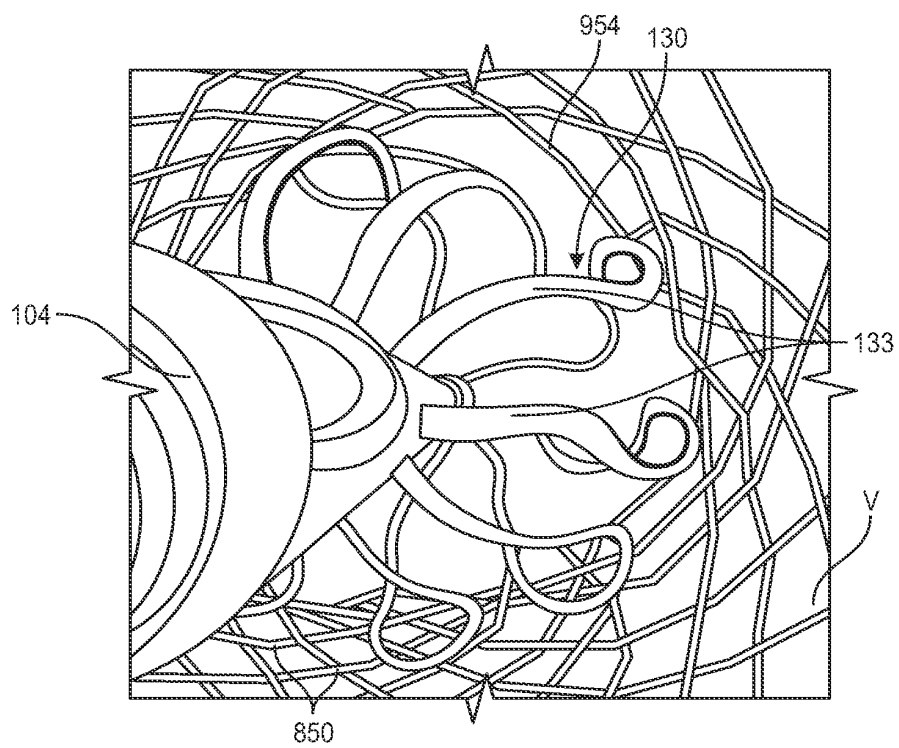


FIG. 9A

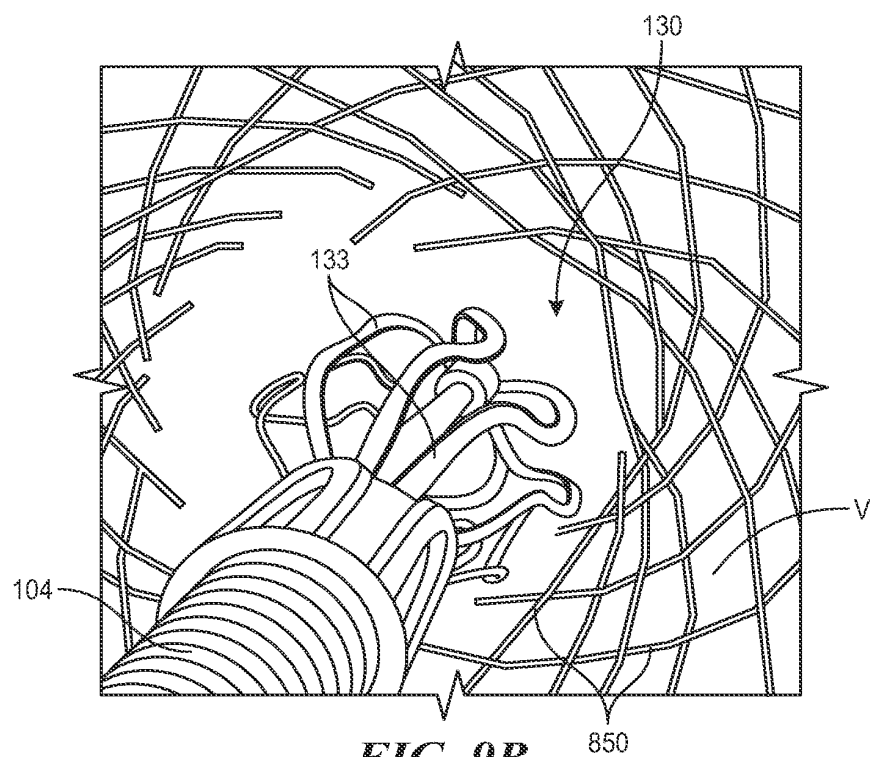
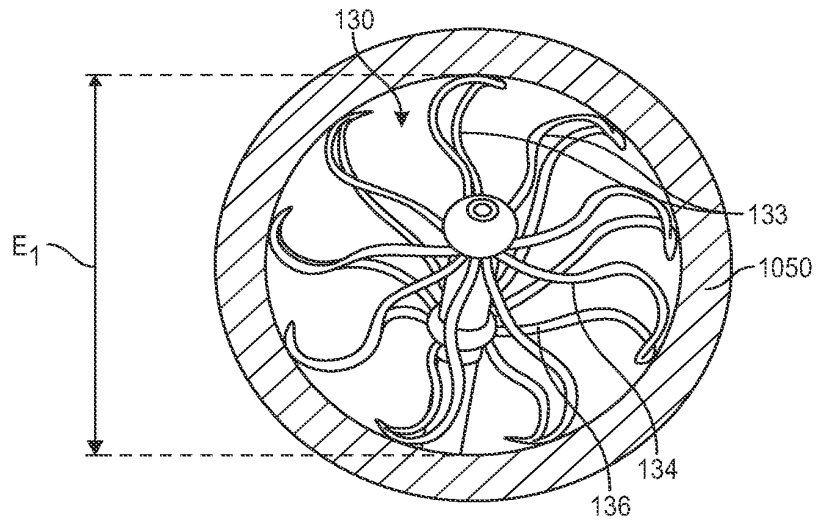
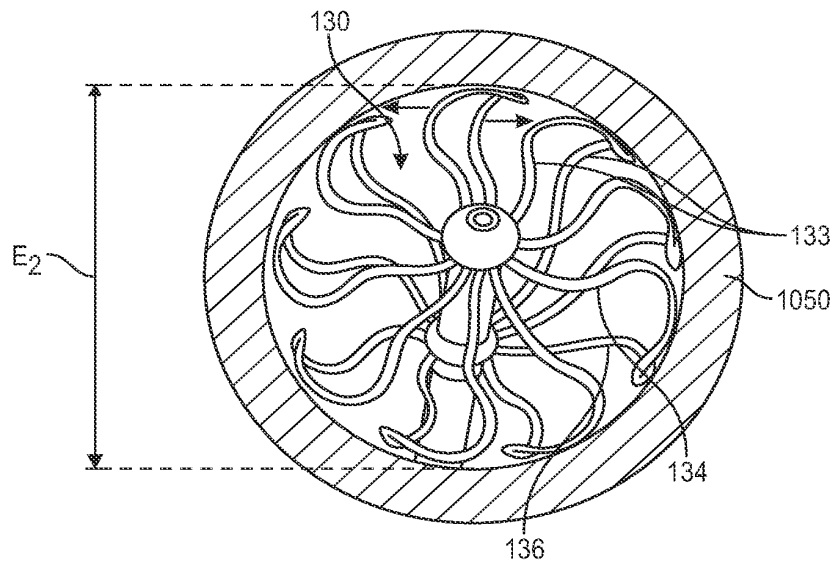
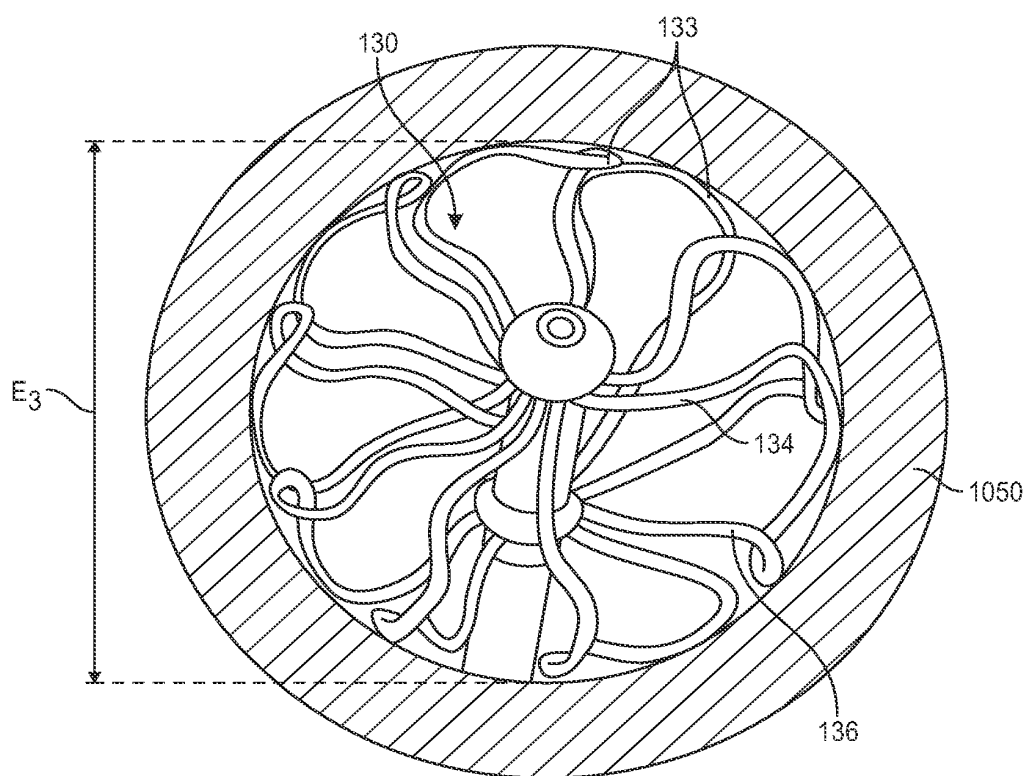
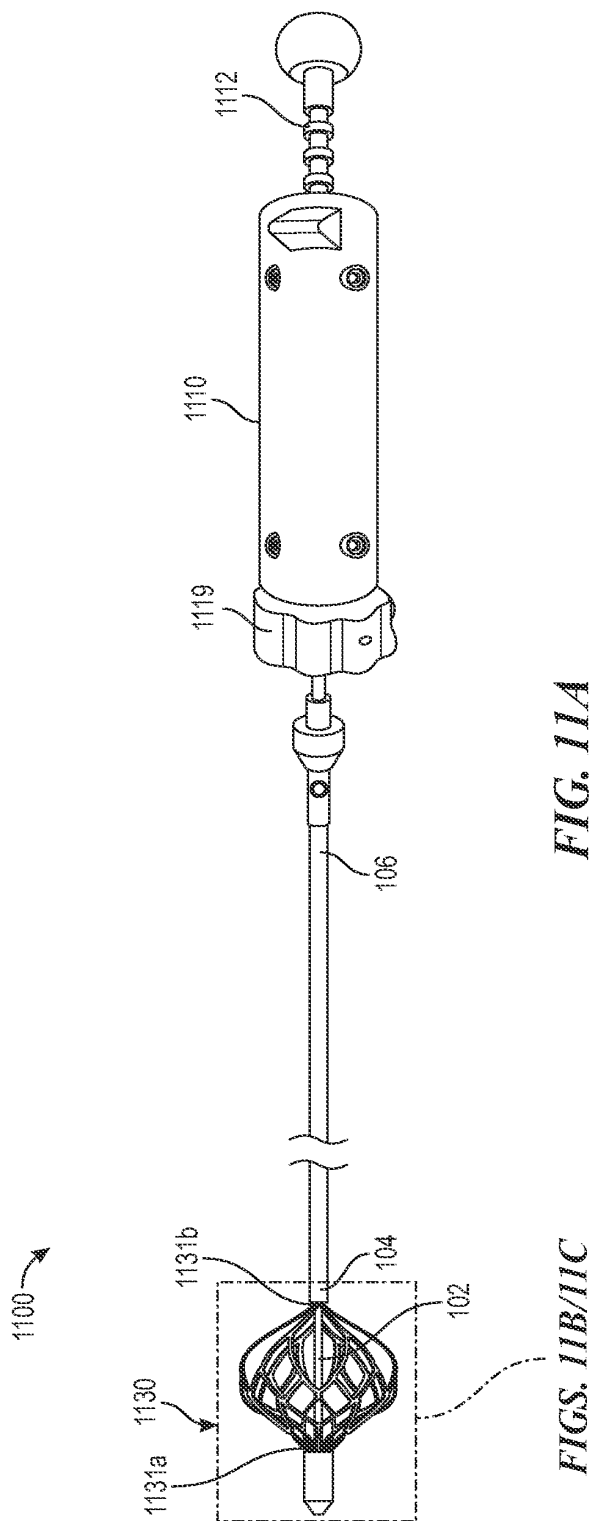
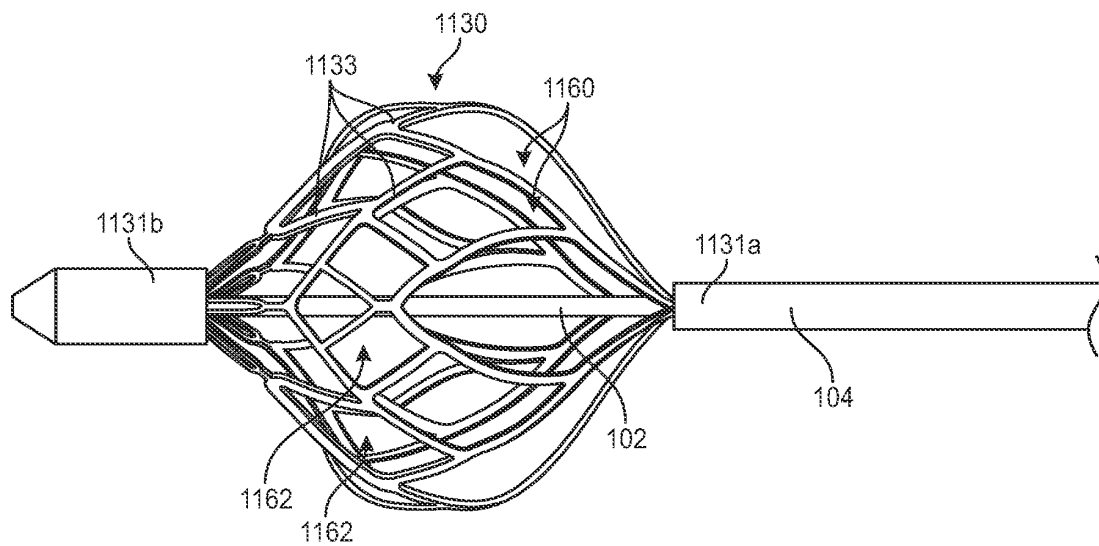
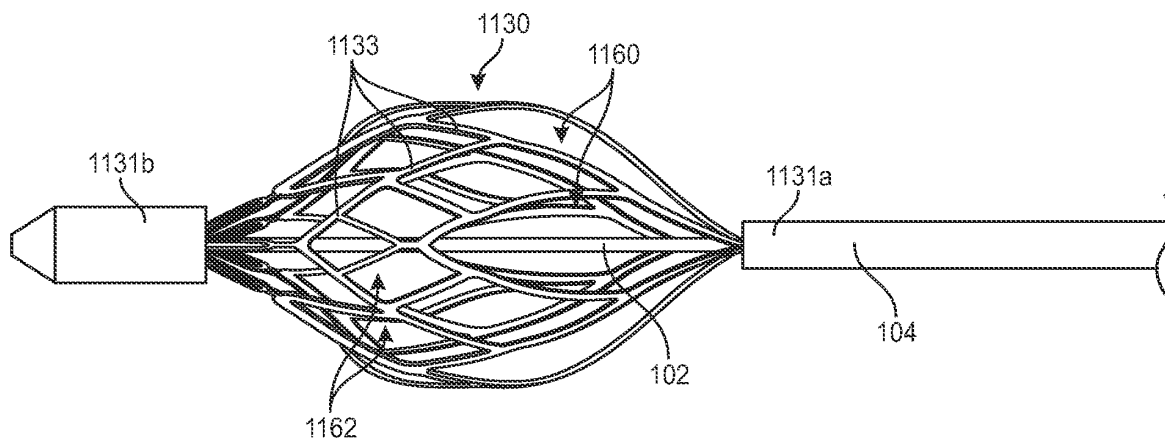


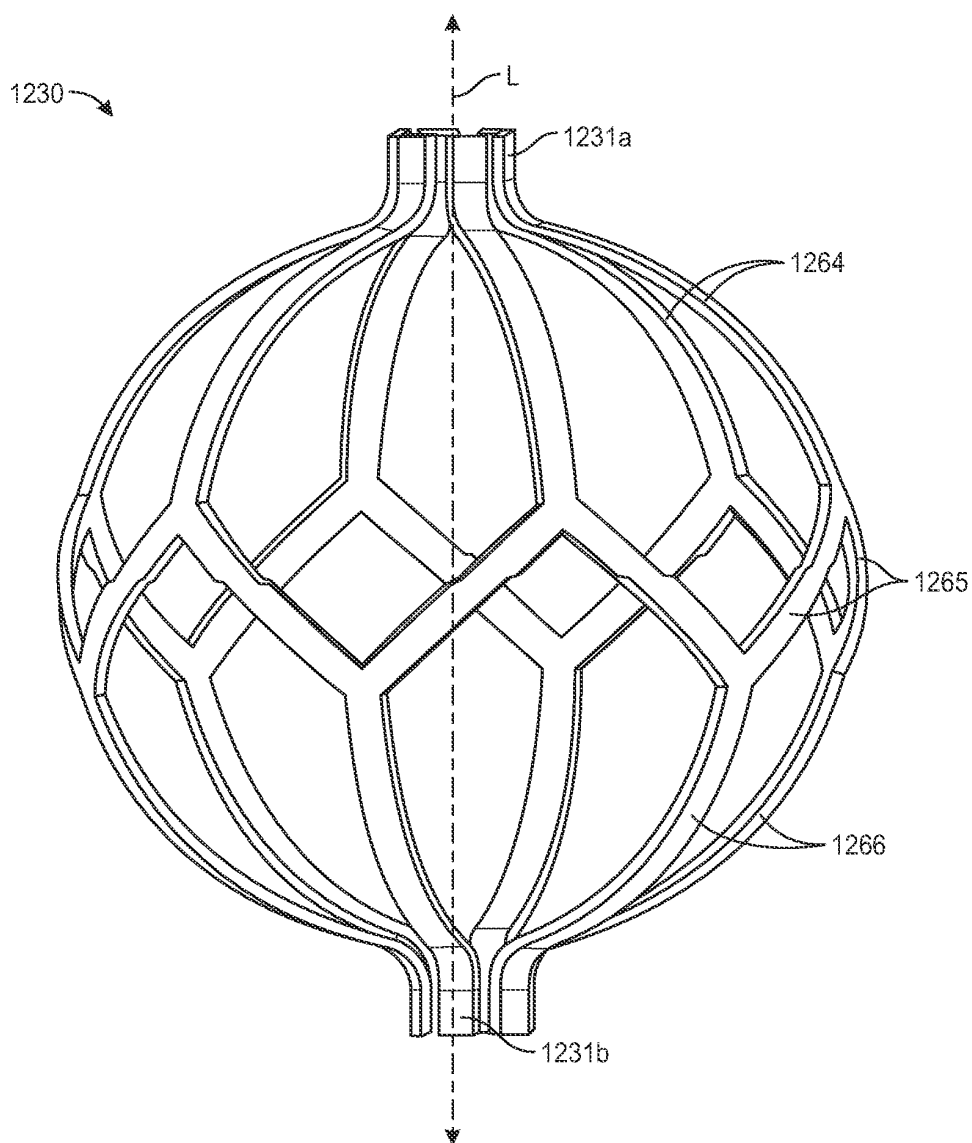
FIG. 9B

**FIG. 10A****FIG. 10B**

**FIG. 10C**



**FIG. 11B****FIG. 11C**

**FIG. 12**

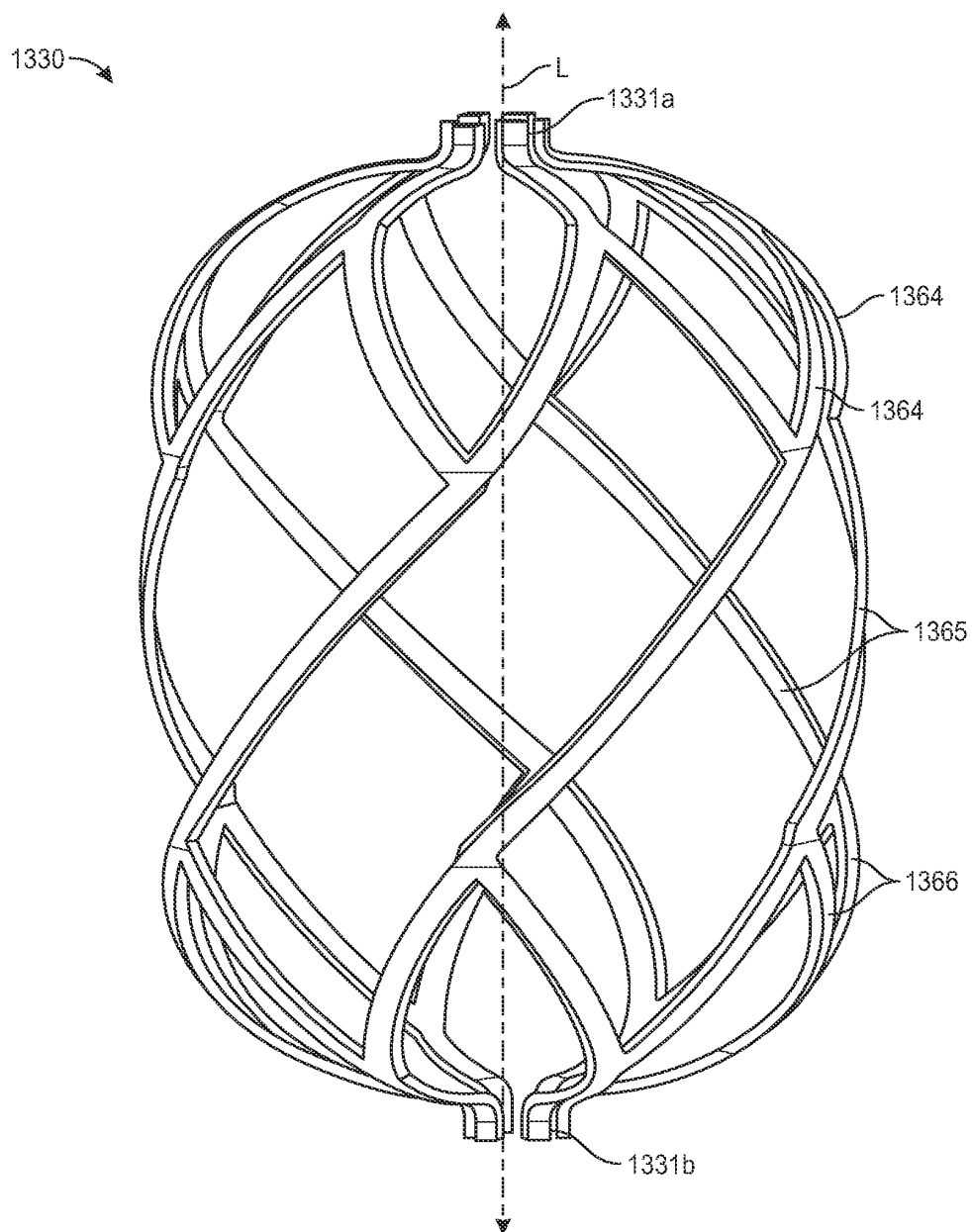
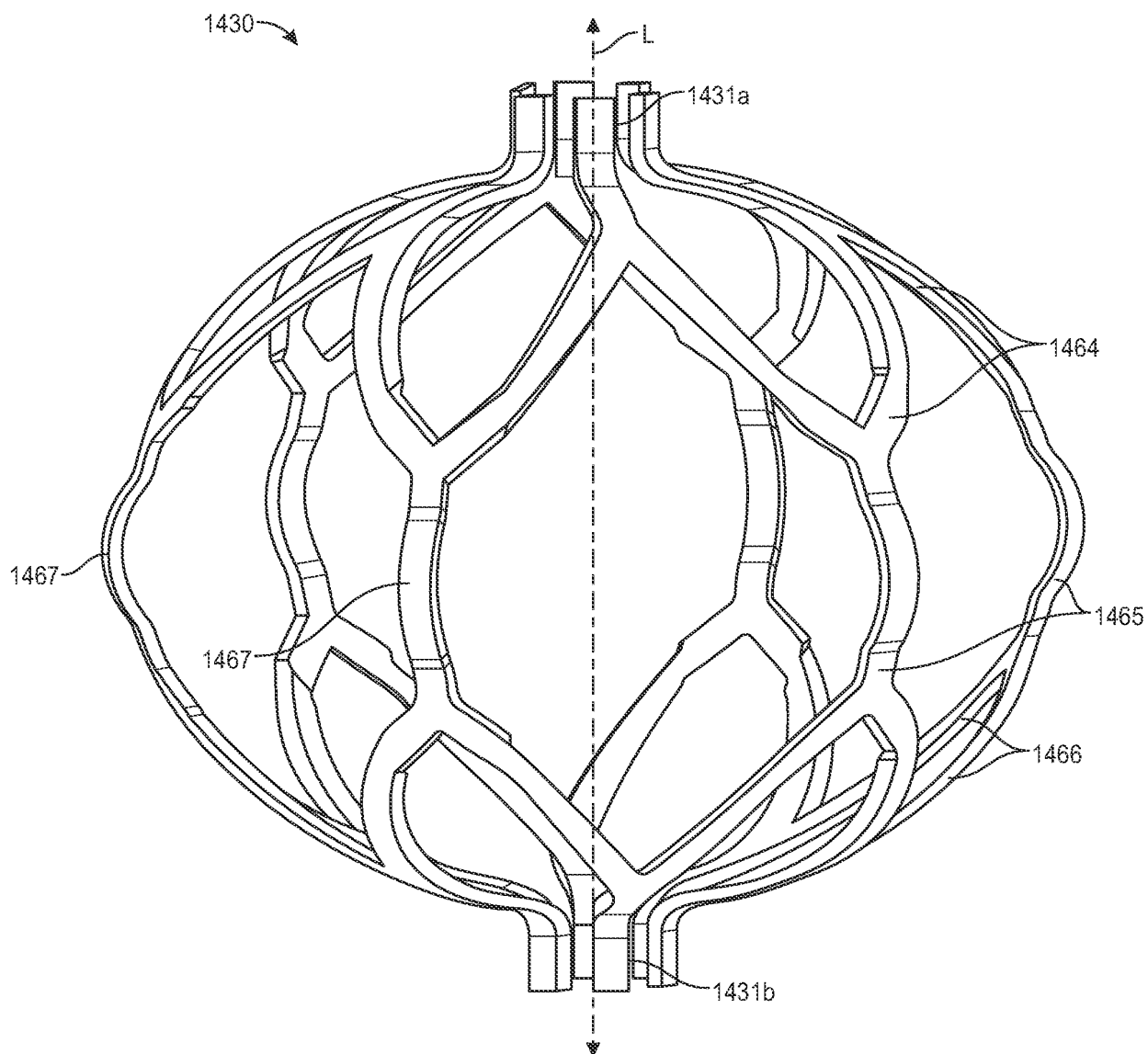
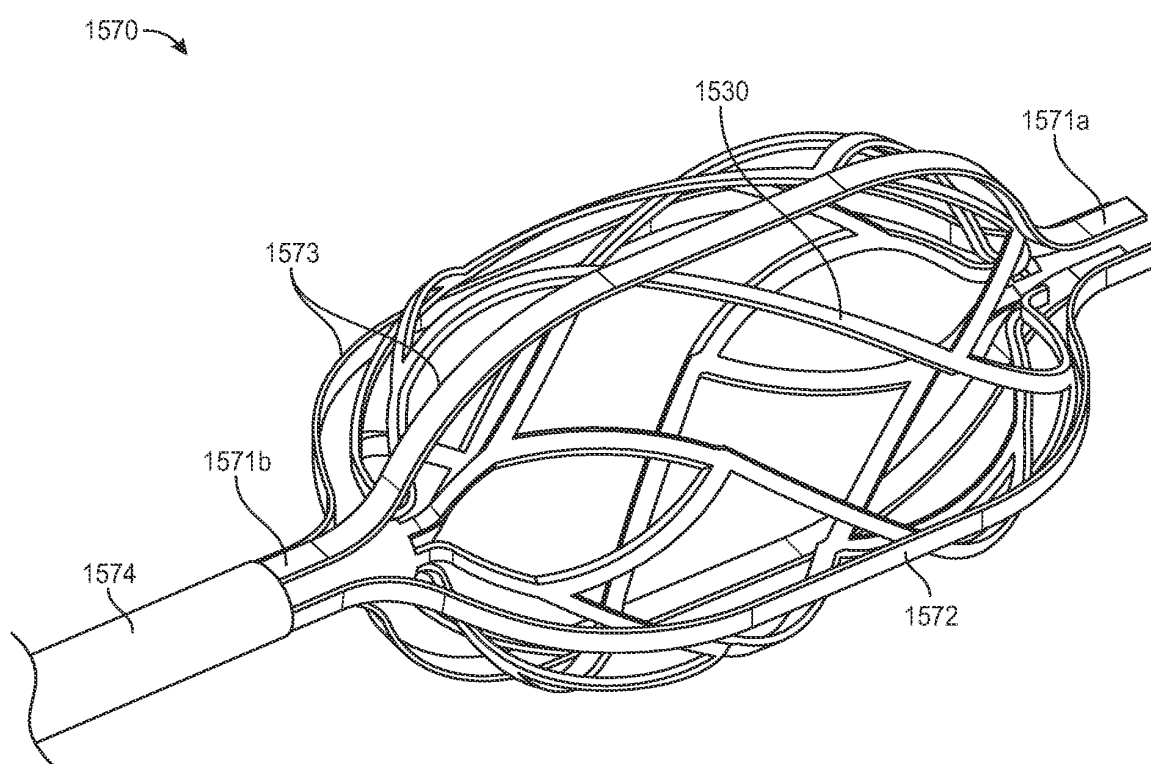


FIG. 13

**FIG. 14**

**FIG. 15**

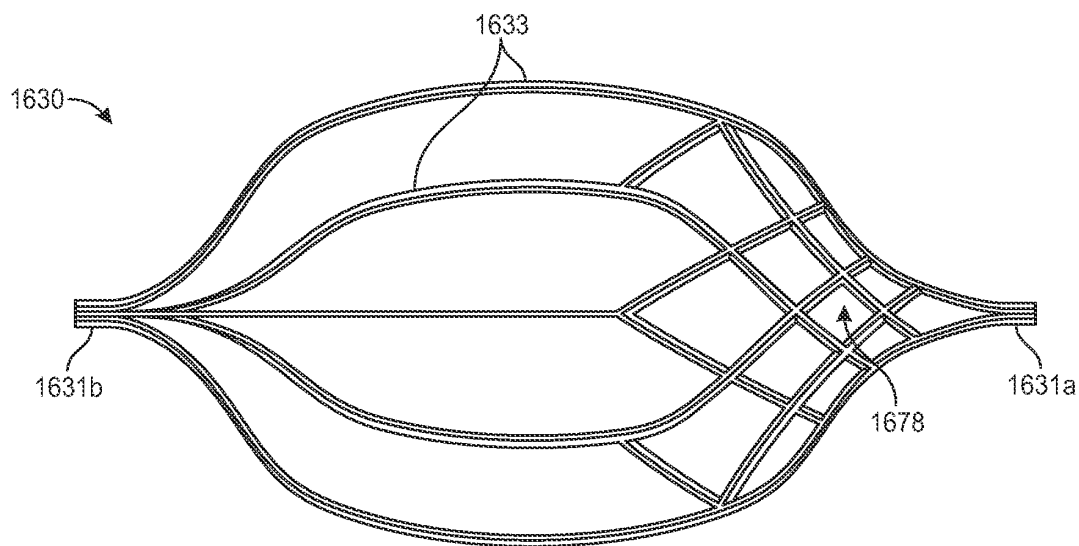


FIG. 16A

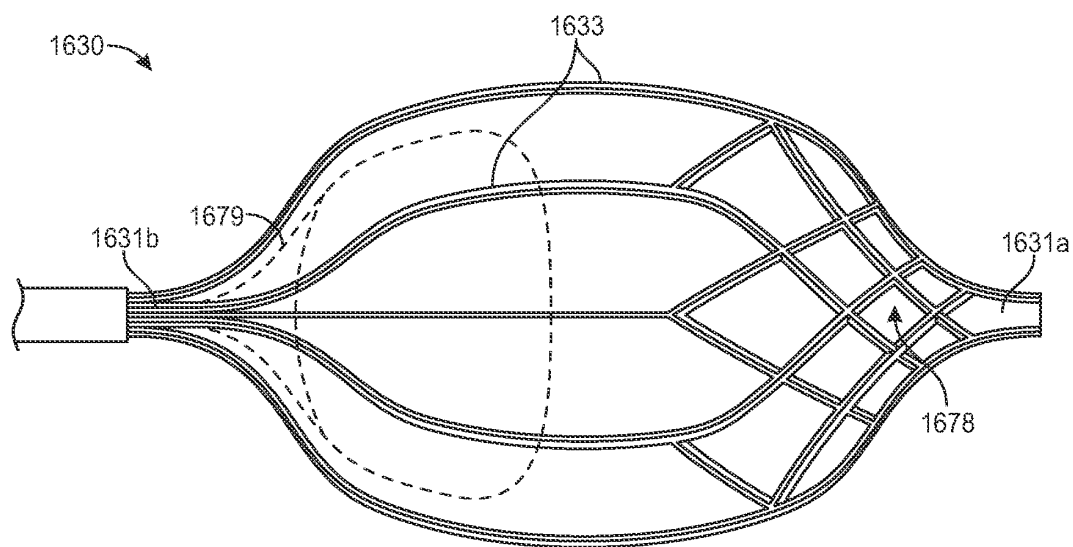


FIG. 16B

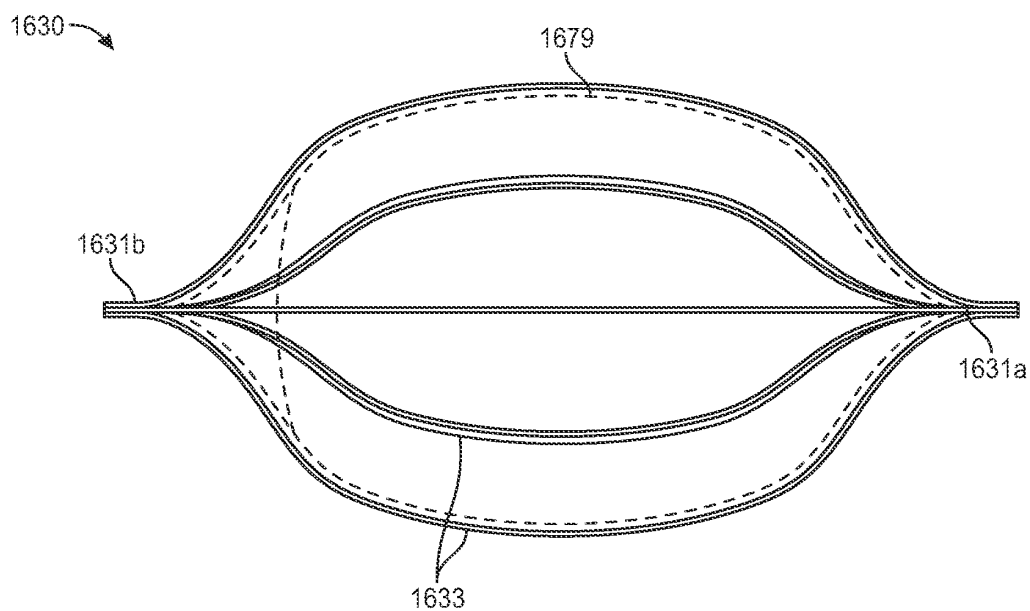


FIG. 16C

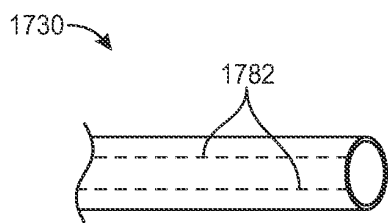


FIG. 17A

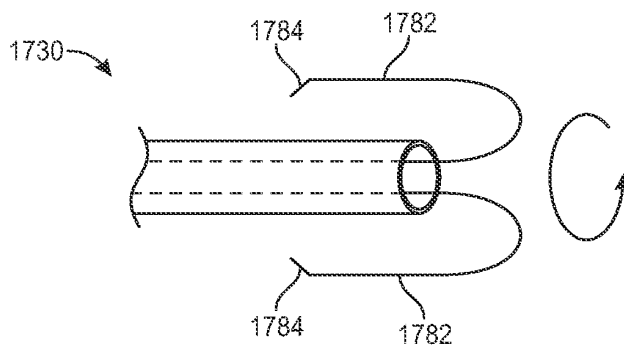


FIG. 17B

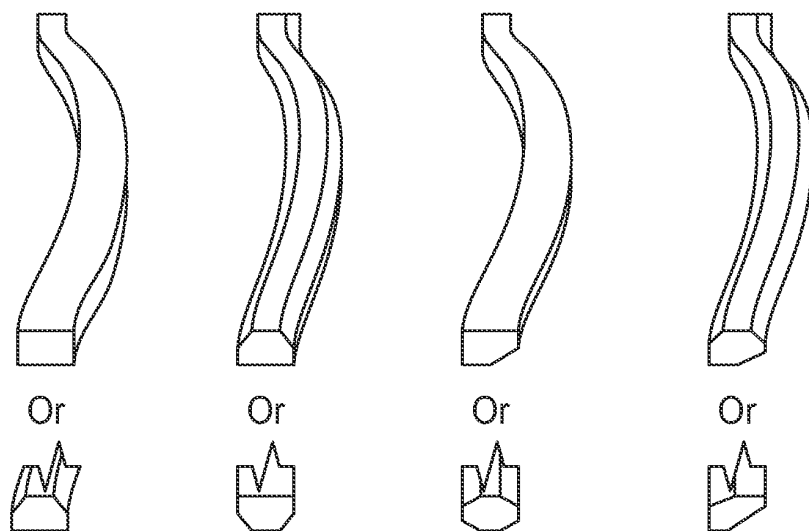


FIG. 18

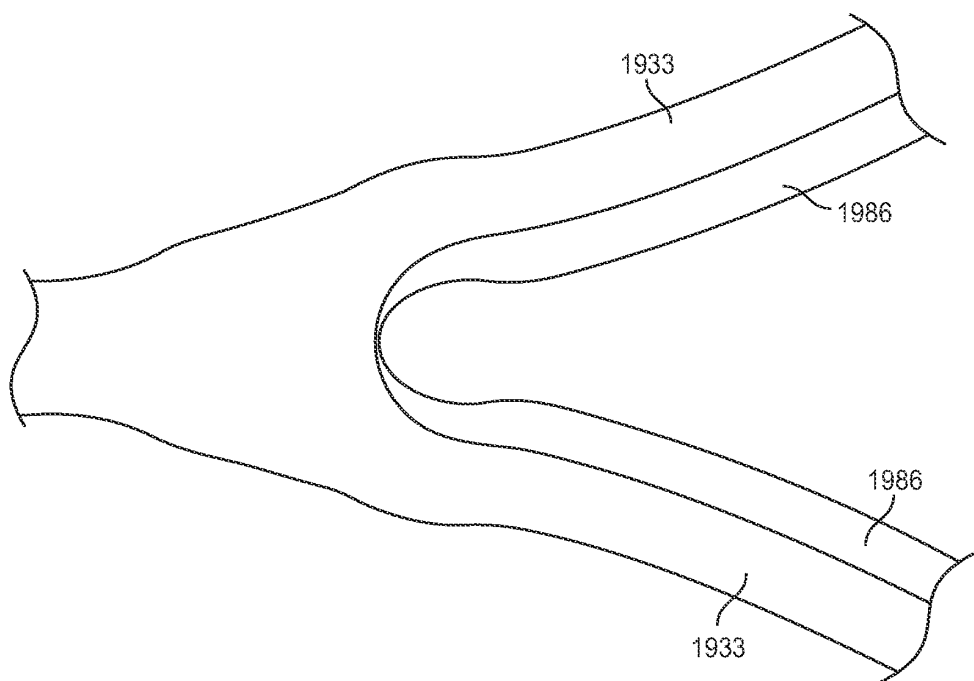


FIG. 19

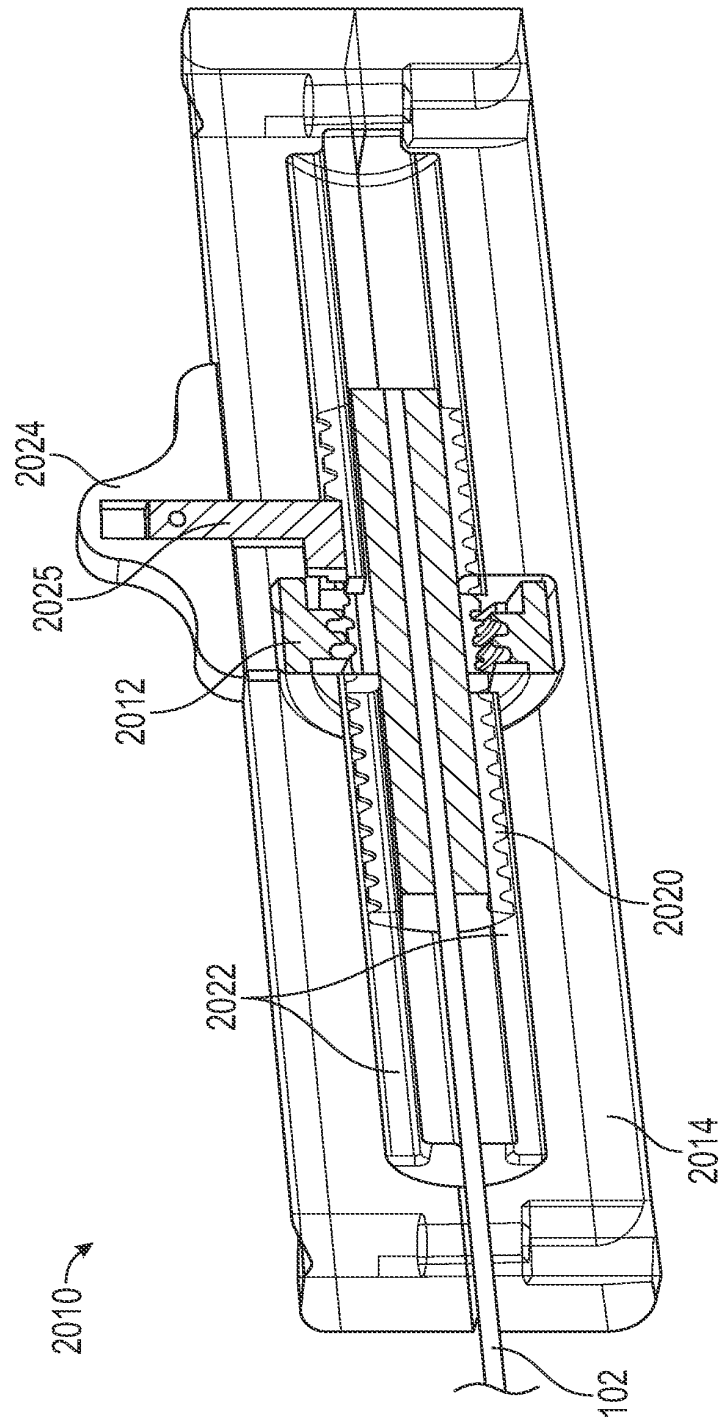


FIG. 20

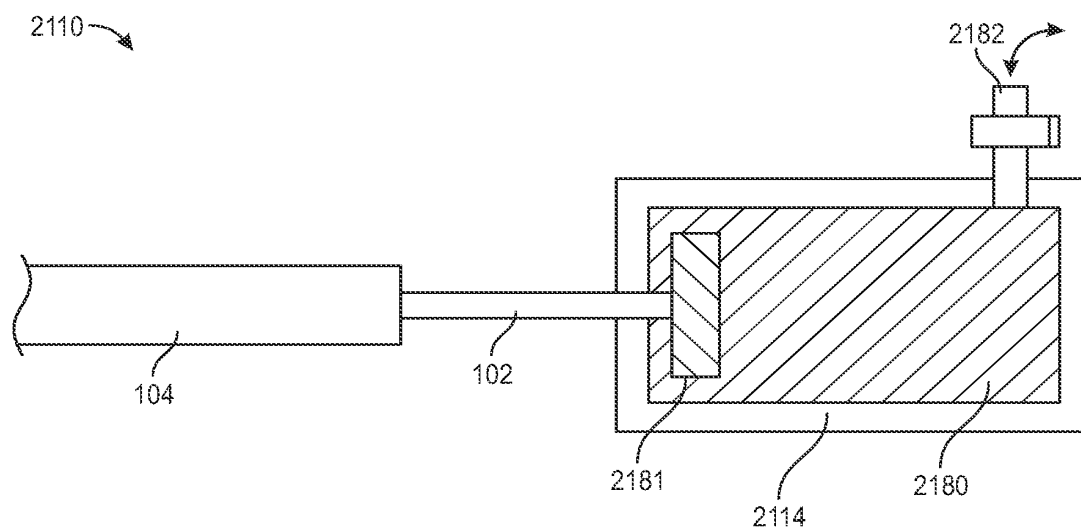


FIG. 21

2290

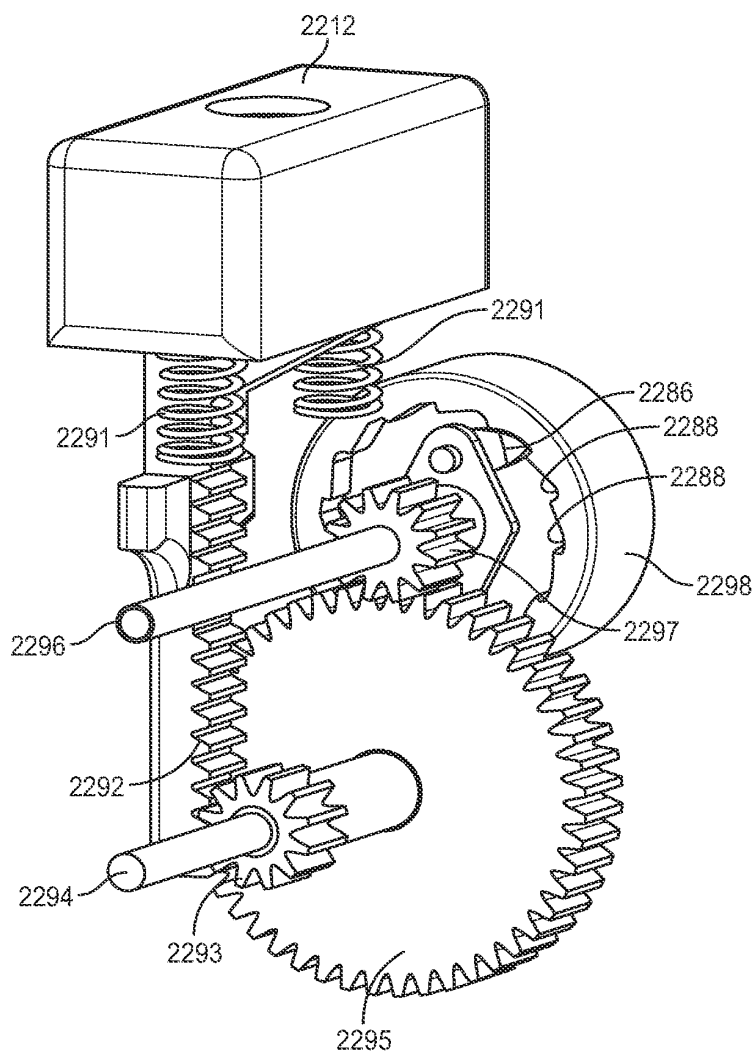


FIG. 22

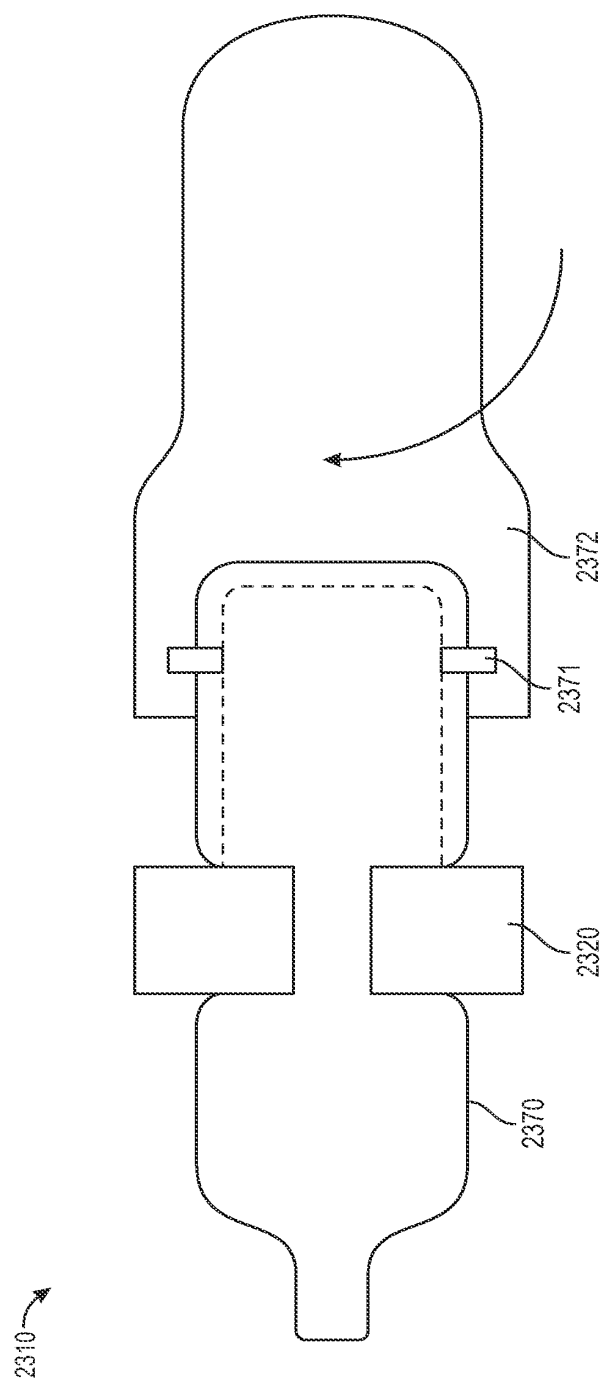
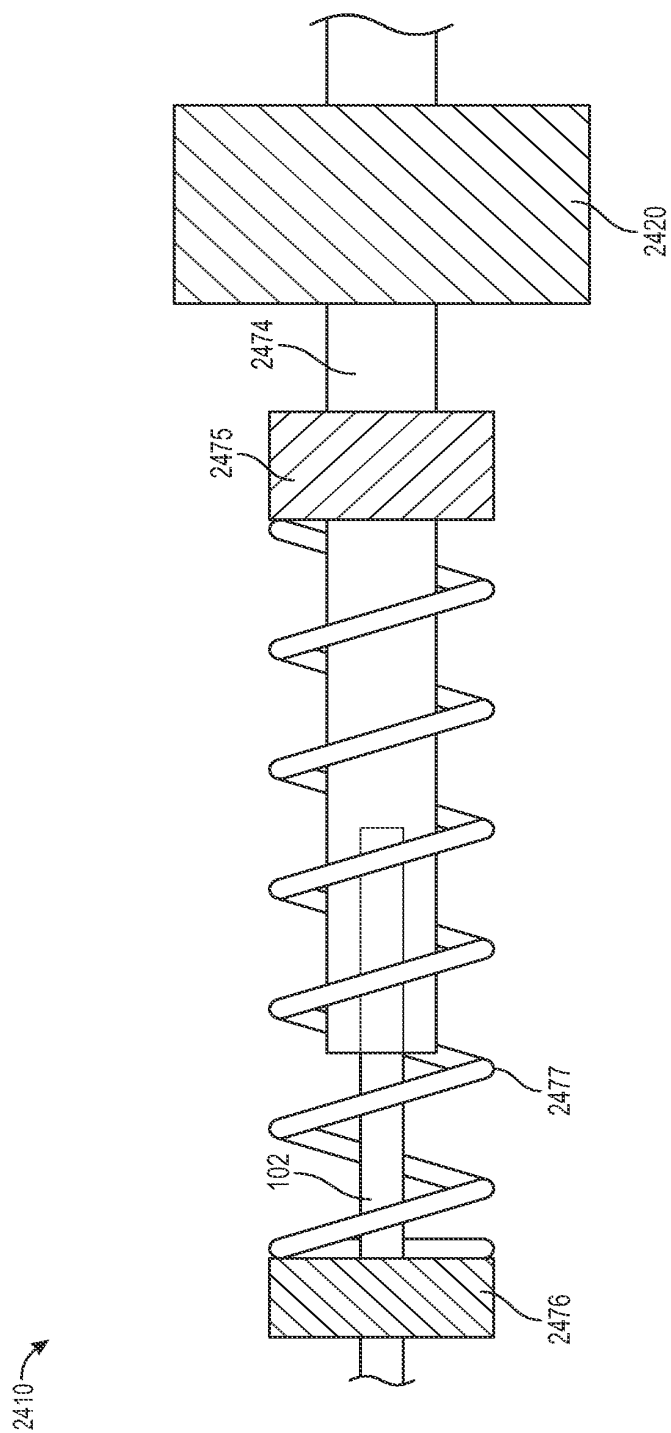
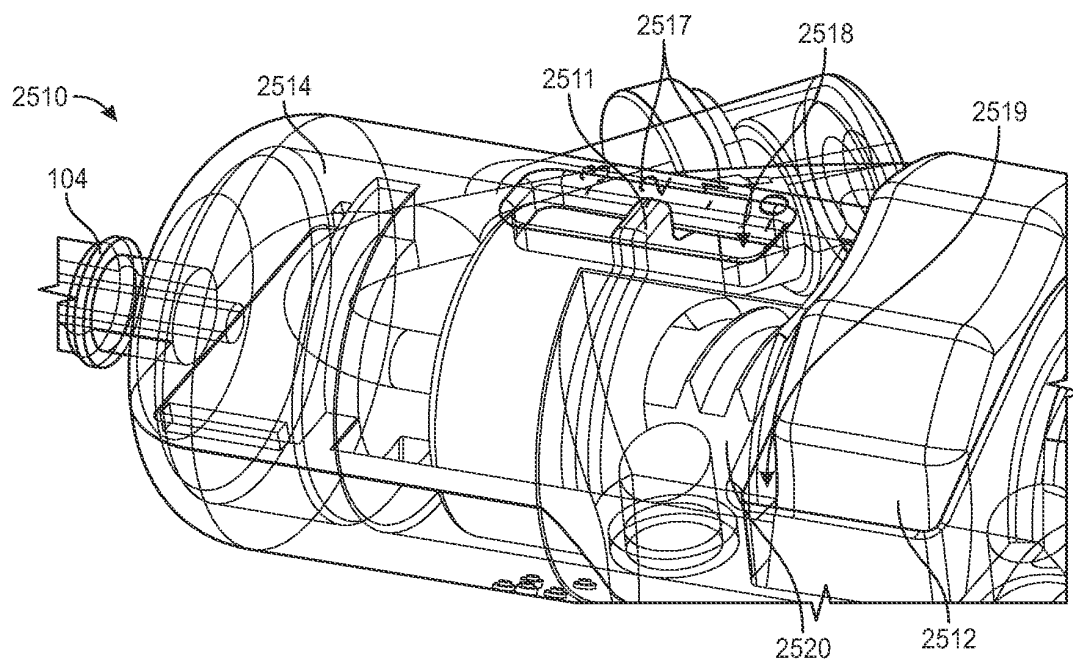
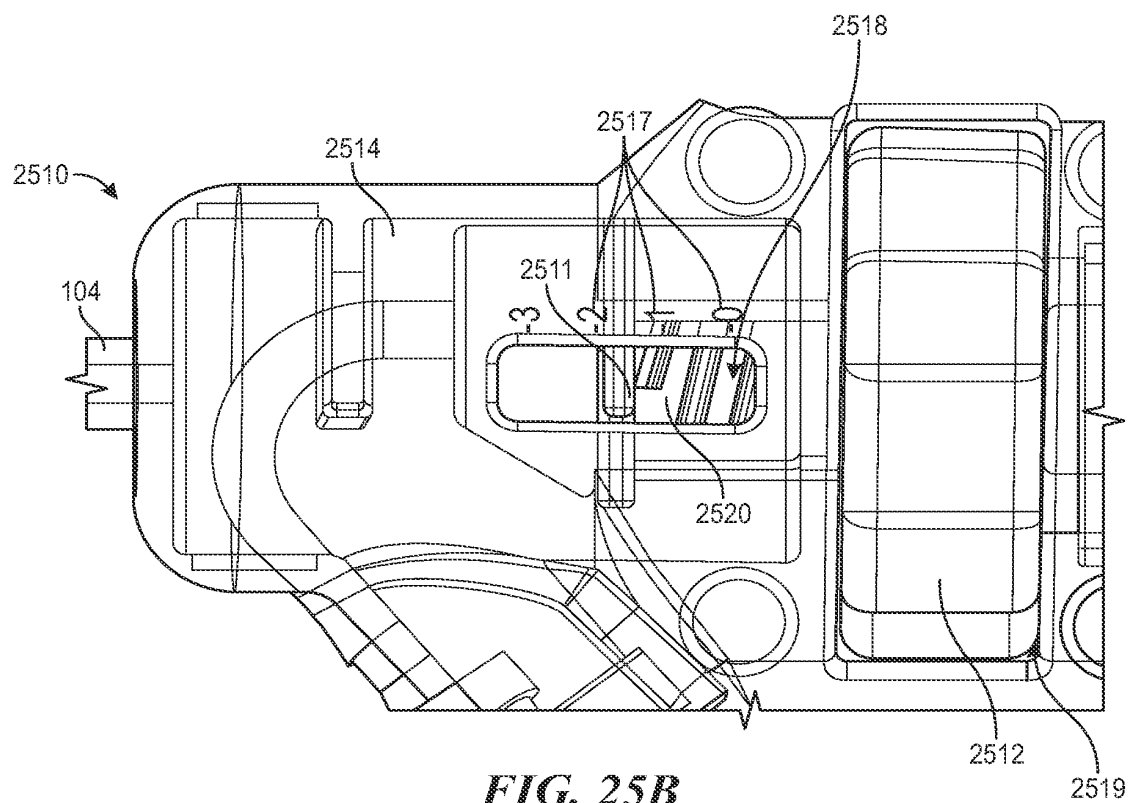


FIG. 23



**FIG. 25A****FIG. 25B**

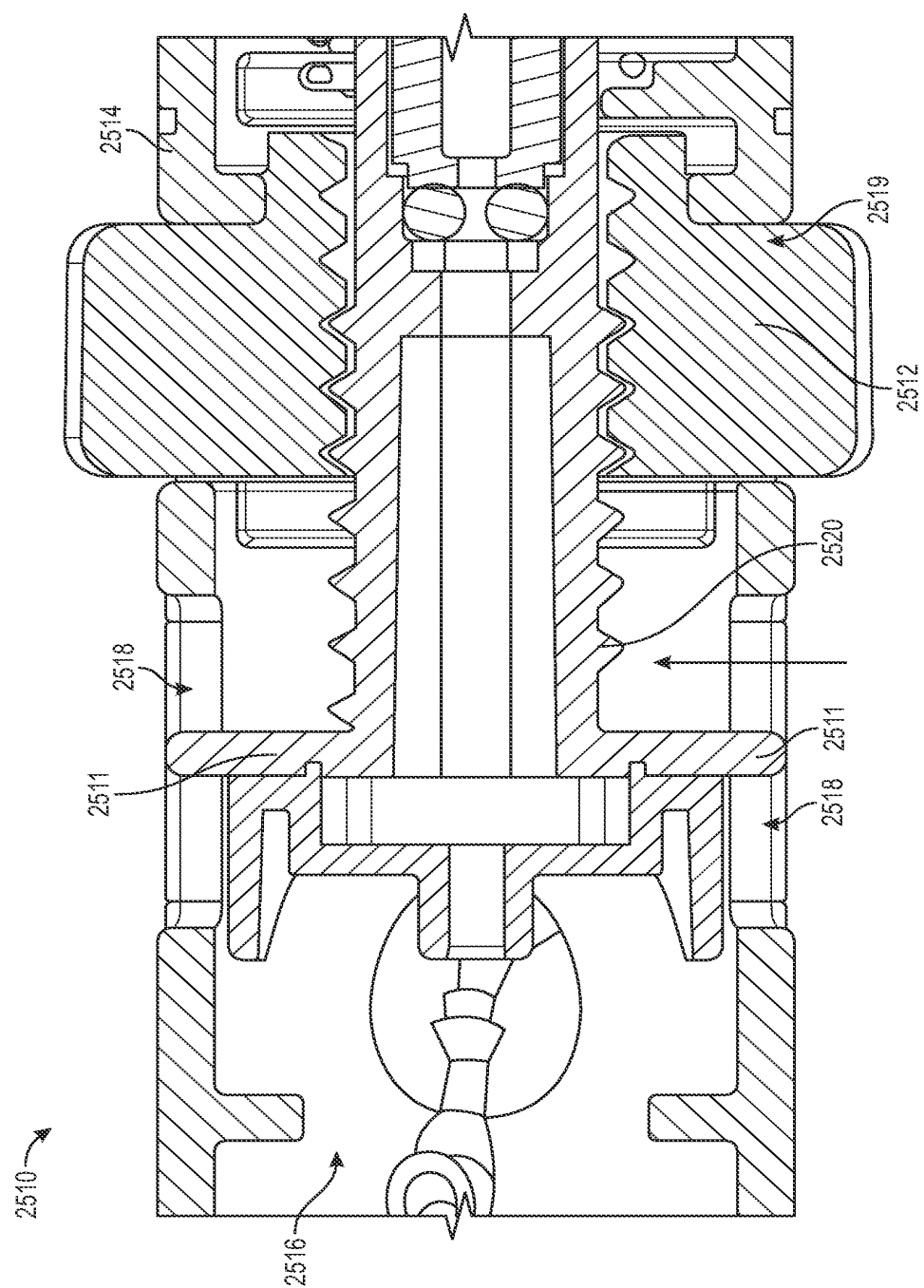


FIG. 25C

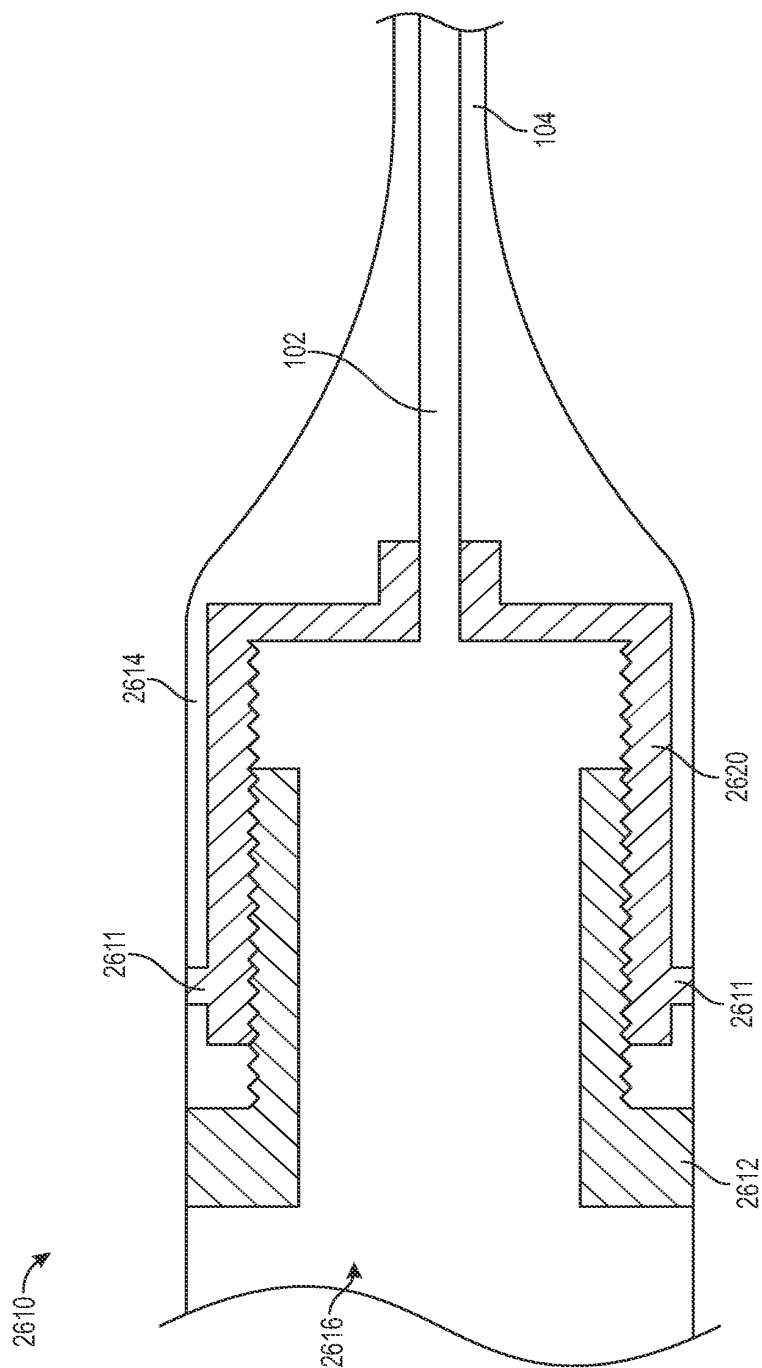


FIG. 26

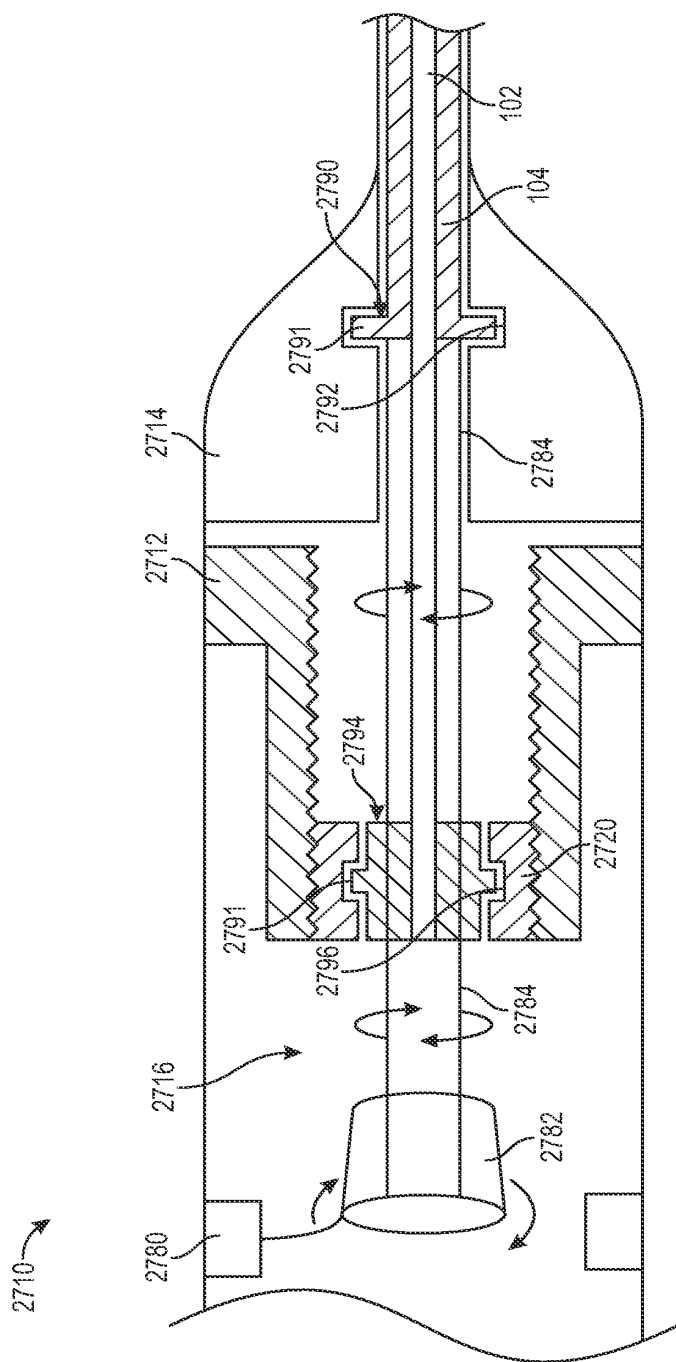


FIG. 27

2800

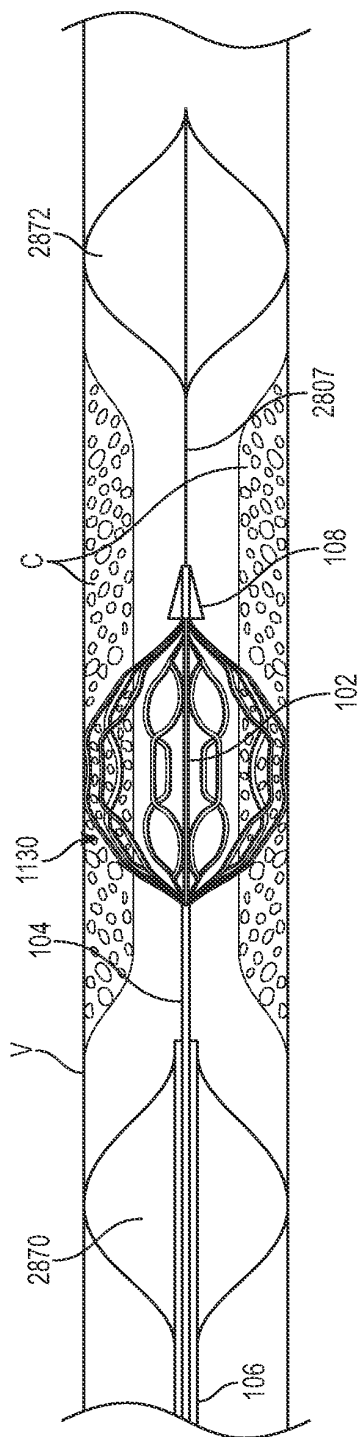


FIG. 28

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60502

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B 17/22, A61B 17/221 (2023.01) IPC - ADD. INV. A61B 17/221 CPC - ADD. A61B 2017/2212 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) See Search History document Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History document Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History document		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 9,301,769 B2 (Brady et al.) 05 April 2016 (05.04.2016), entire document	1-13, 15-20
Y		14
Y	US 2021/0393278 A1 (O'Malley et al.) 23 December 2021 (23.12.2021), entire document	14
A	US 2021/0038385 A1 (Popp et al.) 11 February 2021 (11.02.2021), entire document	1-20
A	US 2005/0203605 A1 (Dolan) 15 September 2005 (15.09.2005), entire document	1-20
☐ 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 22 March 2023		Date of mailing of the international search report MAY 25 2023
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300		Authorized officer Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2022)



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United States Patent and Trademark Office
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P.O. Box 1450
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www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/342,553	06/27/2023		1820	111552.8018.US11	20	3

CONFIRMATION NO. 6799

25096

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

FILING RECEIPT



0000000059475695

Date Mailed: 07/18/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Ben Merritt, San Clemente, CA;
Jacqueline Macias, Fullerton, CA;
Brian Michael Strauss, San Clemente, CA;
Thomas Tu, Louisville, KY;

Applicant(s)

Inari Medical, Inc., Irvine, CA;

Power of Attorney: The patent practitioners associated with Customer Number 25096

Domestic Priority data as claimed by applicant

This application is a CON of 18/167,757 02/10/2023
which is a CON of 17/976,711 10/28/2022
which is a CON of 17/865,315 07/14/2022 PAT 11,642,209
which is a CON of 16/536,185 08/08/2019 PAT 11,559,382
which claims benefit of 62/718,269 08/13/2018
and claims benefit of 62/718,248 08/13/2018

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 07/17/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/342,553**

Projected Publication Date: 10/26/2023

Non-Publication Request: No

Early Publication Request: No

Title

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative,

page 2 of 4

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 18/342,553				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	700			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800			
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	0			x	= 0			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *				x	= 0			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0			
				TOTAL		TOTAL	1820			
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/342,553

RECEIPT DATE / TIME
07/13/2023 07:08:06 PM ET

ATTORNEY DOCKET #
111552.8018.US11

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 6799

FILED BY J iYoung Anderson

PATENT CENTER # 62439671

FILING DATE -

CUSTOMER # 25096

FIRST NAMED INVENTOR Ben Merritt

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NPL_ISR_WO_PCTUS2023060502_May_25_2023_9pages.PDF	9	Non Patent Literature	3976 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
NPL_ISR_WO_PCTUS2023060502_May_25_2023_9pages.PDF	D531F14961694901D7333C4BAA563CF184EF439838AFD5147B2BDDC50612BF18C97B659466792D95F507F17FF02F9D7F5C1806B1068BFC456412E490186AEEF2

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247
RECEIVED PATENT DOCKETING MAY 31 2023 PERKINS COIE LLP

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8034WO00	Date of mailing <i>(day/month/year)</i> MAY 25 2023
International application No. PCT/US 23/60502	International filing date <i>(day/month/year)</i> 11 January 2023 (11.01.2023)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 36 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 36 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1480, Alexandria, Virginia 22313-1480 Facsimile No. 571-273-8300	Authorized officer Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8034WO00		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/JP 23/00502	International filing date (day/month/year) 11 January 2023 (11.01.2023)	(Earliest) Priority Date (day/month/year) 11 January 2022 (11.01.2022)	
Applicant INARI MEDICAL, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(e)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1A
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/00502

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61B 17/22, A61B 17/221 (2023.01)
- ADD.

CPC - INV. A61B 17/221

- ADD. A61B 2017/2212

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 9,301,769 B2 (Brady et al.) 05 April 2016 (05.04.2016), entire document	1-13, 15-20
Y		14
Y	US 2021/0393278 A1 (O'Malley et al.) 23 December 2021 (23.12.2021), entire document	14
A	US 2021/0038385 A1 (Popp et al.) 11 February 2021 (11.02.2021), entire document	1-20
A	US 2005/0203605 A1 (Dolan) 15 September 2005 (15.09.2005), entire document	1-20

☐ 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

"I" 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

22 March 2023

Date of mailing of the international search report

MAY 25 2023

Name and mailing address of the ISA/IJS

Mail Stop PCT, Attn: ISA/IJS, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Karl Rodriguez

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2022)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MATTHEW S. WILLIAMS PERKINS COIE LLP P.O. BOX 1247 SEATTLE, WA 98111-1247			RECEIVED PATENT DOCKETING MAY 31 2023 PERKINS COIE LLP		
Applicant's or agent's file reference 111552-8034WO00			FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US 23/80502	International filing date (day/month/year) 11 January 2023 (11.01.2023)	Priority date (day/month/year) 11 January 2022 (11.01.2022)			
International Patent Classification (IPC) or both national classification and IPC IPC . A61B 17/22, A61B 17/221 (2023.01) ADD. INV. A61B 17/221 CPC . ADD. A61B 2017/2212					
Applicant INARI MEDICAL, INC.					

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(s)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(h) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 22 March 2023	Authorized officer Karl Rodriguez PCT Help Desk Telephone No. 571-272-4300
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Form PCT/ISA/237 (cover sheet) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JS 23/60502

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(h)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

- a. ☐ forming part of the international application as filed.
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(s)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 23/60502

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-20	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-13 and 15-20 lack novelty under PCT Article 33(2) as being anticipated by US 9,301,769 B2 to Brady et al. (hereinafter "Brady").

Regarding claim 1, Brady teaches a system for removing clot material from an implant positioned within a body vessel (Fig 1a; col 1, in 31-36), comprising:

a clot treatment device (device 1, Fig 1a; col 44, in 23-38) configured to be deployed within the implant,

wherein the clot treatment device includes a first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9), a second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28), and a plurality of struts (882, 883, Fig 35a; col 56, in 9-10) extending between the first end portion and the second end portion (see Fig 35a);

a handle including an actuator (11, Fig 1a; col 44, in 39-43, see discussion wherein physician is able to manually control the device via the handle);

a first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9), coupling the first end portion of the clot treatment device to the handle (see Fig 1a); and

a second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) coupling the second end portion of the clot treatment device to the handle (see Fig 1a),

wherein actuation of the actuator is configured to move the second elongate member relative to the first elongate member to reduce a distance between the first end portion and the second end portion to radially expand the struts (see first position of device in Fig 35b and second position of device in Fig 35a; col 44, in 39-46, see discussion wherein the handle is used to control and move the capture net).

Regarding claim 2, Brady teaches the system of claim 1. Brady further teaches wherein the implant is a stent (col 3, in 31-36; col 3, in 29-38).

Regarding claim 3, Brady teaches the system of claim 1. Brady further teaches wherein the first end portion is a proximal end portion of the clot treatment device (see where 885 is at end 890 and 893, Fig 35a; col 56, in 3-9), and

wherein the second end portion is a distal end portion of the clot treatment device (see end at distal collar 887, Fig 35b; col 56, in 23-28).

Regarding claim 4, Brady teaches the system of claim 3. Brady further teaches wherein the second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) extends through a lumen (col 19, in 43-49) of the first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9).

Regarding claim 5, Brady teaches the system of claim 1. Brady further teaches wherein the first end portion is a distal end portion of the clot treatment device, and wherein the second end portion is a proximal end portion of the clot treatment device (see Figs 1a and 35a, wherein the positioning of the end portions 893 and 887 is reflective about the perpendicular axis to the longitudinal axis of the elongate shaft 9 that coupled to the handle 11).

Regarding claim 6, Brady teaches the system of claim 1. Brady further teaches wherein actuation of the actuator is configured to move both the first elongate member and the second elongate member relative to the handle (see first position at 35b and second position at 35a; col 56, in 10-14; col 44, in 39-44).

Regarding claim 7, Brady teaches the system of claim 1. Brady further teaches wherein the handle is rotatable to rotate the clot treatment device relative to the implant (see flexibility of elongate shaft 9 relative to handle 11 shown as rotatable in Fig 1a).

Regarding claim 8, Brady teaches the system of claim 1. Brady further teaches wherein the handle is longitudinally movable to move the clot treatment device longitudinally relative to the implant (see handle in Fig 1a; col 44, in 39-43; col 56, in 10-14).

- Continued in Supplemental Box -

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/00502

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 15. Lack of antecedent basis for "the second elongate member" and "the first elongate member"

Claim 18. Semantics... "compressing" should be "comprising"

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 23/60502

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

- Box V.2. Citations and explanations -

Regarding claim 9, Brady teaches the system of claim 1. Brady also teaches wherein the handle is rotatable and longitudinally movable to rotate and longitudinally move the clot treatment device relative to the implant (see flexibility of elongate shaft 9 relative to handle 11 shown as rotatable in Fig 1a; col 44, in 39-43; col 56, in 10-14).

Regarding claim 10, Brady teaches the system of claim 1. Brady further teaches comprising a guide catheter (889, Fig 35b; col 7, in 13-21; col 26, in 8-31).

wherein the clot treatment device is configured to be

(a) covered within the guide catheter in a first state (889, Fig 35b; col 26, in 8-31) and

(b) uncovered from the guide catheter and expanded to a second state (Fig 35a; col 26, in 8-31).

Regarding claim 11, Brady teaches the system of claim 1. Brady further teaches wherein the struts extend generally axially between the first and second end portions and each have an undulating shape (882 and 883, Fig 35a; col 56, in 3-16).

Regarding claim 12, Brady teaches the system of claim 1. Brady further teaches

wherein the struts each extend axially between the first and second end portions (882 and 883, Fig 35a; col 56, in 3-16), and

wherein the clot treatment device does not include any crossmembers interconnecting the struts (Fig 35a).

Regarding claim 13, Brady teaches the system of claim 1. Brady further teaches wherein the actuator is a rotatable knob or a slider (handle 11, Fig 1a; col 12, in 3-42, wherein the handle actuates the expandable body to slide through a micro lumen).

Regarding claim 15, Brady teaches a method of removing clot material from an implant positioned within a body vessel (Fig 1a; col 1, in 31-36), the method comprising:

positioning a clot treatment device (device 1, Fig 1a; col 44, in 23-39) at least partially within the implant,

wherein the clot treatment device has

(a) a first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9),

(b) a second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28), and

(c) a plurality of struts (882 and 883, Fig 35a; col 56, in 9-10) extending between the first end portion and the second end portion (see Fig 35a)

moving the second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9) relative to the first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9) to reduce a distance between the first end portion and the second end portion to radially expand the struts (see first position of device in Fig 35b and second position of device in Fig 35a; col 44, in 39-46, see discussion wherein the handle is used to control and move the capture net); and

after radially expanding the struts, rotating and/or translating the clot treatment device within the implant to materially engage the clot material with at least a portion of the struts (col 26, in 8-31).

Regarding claim 16, Brady teaches the method of claim 15. Brady further teaches

wherein the first end portion (see collar 885 at proximal end 893, Fig 35a; col 56, in 3-9) of the clot treatment device is coupled to a first elongate member (shaft distal end 890, Fig 56a; col 56, in 3-9),

wherein the second end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28) of the clot treatment device is coupled to a second elongate member (see elongate shaft 9 in Fig 1a and at distal stop 888, Fig 56a; col 56, in 3-9), and

wherein moving the second elongate relative to the first elongate member comprises

actuating an actuator on a handle (11, Fig 1a; col 44, in 39-43, see discussion wherein physician is able to manually control the device via the handle) coupled to the first elongate member and the second elongate member (Figs 1a and 35a) to move the second elongate member relative to the first elongate member (see first position at 35b and second position at 35a; col 56, in 10-14; col 44, in 39-44; col 26, in 8-31).

Regarding claim 17, Brady teaches the method of claim 15. Brady further teaches wherein the struts each extend axially between the first and second end portions (882 and 883, Fig 35a; col 56, in 3-16), and

wherein the clot treatment device does not include any crossmembers interconnecting the struts (Fig 35a).

Regarding claim 18, Brady teaches the method of claim 15. Brady further teaches wherein the implant is a stent (col 3, in 31-36; col 3, in 29-36).

- Continued in Supplemental Box -

Form PCT/ISA/237 (Supplemental Box) (revised July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 23/60602

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

- Preceding Supplemental Box for V.2. Citations and explanations -

Regarding claim 19, Brady teaches a clot treatment device (device 1, Fig 1a; col 44, in 23-39) comprising:

a proximal end portion (see collar 885 at proximal end 890 and 893, Fig 35a; col 56, in 3-8);

a distal end portion (see end at distal collar 887, Fig 35b; col 56, in 23-28; and

a plurality of struts extending generally axially along a longitudinal axis between the proximal end portion and the distal end portion (882 and 883, Fig 35a; col 56, in 9-10),

wherein movement of the first end portion toward the second end portion is configured to radially expand the struts (see first position of device in Fig 35h and second position of device in Fig 35a; col 56, in 3-12);

Individual ones of the struts include

a proximal portion extending from the proximal end portion (see struts 882 and 883 at proximal end 890, Fig 35a),

a distal portion extending from the distal end portion (see struts at distal end near 887, Fig 35a), and

a middle portion (see additional embodiment Figs 6 and 7)

(a) extending between the proximal portion and the distal portion (Figs 6 and 7) and

(b) having a hook-like shape in a direction about the longitudinal axis (Figs 6 and 7; col 49, in 53-58); and

individual ones of the struts have an undulating shape in a direction along the longitudinal axis (see struts 882 and 883, Fig 35a).

Regarding claim 20, Brady teaches the clot treatment device of claim 19. Brady further teaches wherein the clot treatment device does not include any cross-members interconnecting the struts (Figs 6, 7, and 35a).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over Brady in view of US 2021/0383278 A1 to O'Malley et al. (hereinafter "O'Malley").

Regarding claim 14, Brady teaches the system of claim 1. Brady does not specifically teach wherein the handle includes an indicator configured to indicate an amount that the struts are radially expanded. However, Brady teaches the handle operating an activation cable from the shaft to advance the radial struts that expand in operation (Figs 1a and 35a; col 56, in 3-14). Further, O'Malley teaches wherein the handle (shaft 106, Fig 1A; para [0097]) includes an indicator configured to indicate an amount that the struts are radially expanded (see indicator bands 107, Fig 1A; para [0097]). Accordingly, it would have been obvious to a person of ordinary skill in the art to combine a system for removing clot material as in Brady with a handle including an indicator configured to indicate an amount that the struts are radially expanded as in O'Malley so as to provide for an indication of advancement of the system into a patient.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew S. Williams Perkins Coie LLP P.O. Box 1247 Seattle, WA 98111-1247 United States Of America
RECEIVED PATENT DOCKETING JUN 12 2023 PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8035WO00	Date of mailing <i>(day/month/year)</i> JUN 07 2023
International application No. PCT/US23/61256	International filing date <i>(day/month/year)</i> 25 January 2023 (25.01.2023)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.
 Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).
 When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.
 How? Directly to the International Bureau preferably through ePCT, or on paper to:
 The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

 For more detailed instructions, see the *PCT Applicant's Guide, International Phase*, paragraphs 9.004 -- 9.011.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Reminders
 The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.
 Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).
 Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 28 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide, National Chapters*.
 Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide, International Phase*, paragraphs 8.006-8.032.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1480, Alexandria, Virginia 22313-1480 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8035W000		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US23/61258	International filing date (day/month/year) 25 January 2023 (25.01.2023)	(Earliest) Priority Date (day/month/year) 31 January 2022 (31.01.2022)	
Applicant INARI MEDICAL, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequences disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 3A
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/61258

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 1/00 (2023.01)

ADD. A61B 17/22; A61M 25/00 (2023.01)

CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005

ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2205/15; A61M 2205/20

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/0030708 A1 (ANGIODYNAMICS INC.) 04 February 2016; figures 4, 8b; paragraphs 0008, 0009, 0030, 0036, 0038, 0039; abstract; claim 3	1-13, 15-21
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Y		14
X	US 2016/0135529 A1 (ANGIODYNAMICS INC.) 19 May 2016; figures 2a-4c, 7; paragraphs 0037, 0049	22-24
Y	US 2008/0264905 A1 (ESKRIDGE ET AL.) 23 November 2006; paragraphs 0005, 0027	14
A	US 5,244,619 A (BURNHAM) 14 September 1993; entire document	1-24
A	US 2017/0021130 A1 (DYE) 26 January 2017; entire document	1-24

☐ 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

"Z" document member of the same patent family

Date of the actual completion of the international search

24 April 2023 (24.04.2023)

Date of mailing of the international search report

JUN 07 2023

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2022)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Matthew S. Williams Perkins Coie LLP P.O. Box 1247 Seattle, WA 98111-1247 United States Of America
RECEIVED PATENT DOCKETING JUN 12 2023 PERKINS COIE LLP

Date of mailing (day/month/year)	JUN 07 2023
-------------------------------------	--------------------

Applicant's or agent's file reference 111552-6035W000		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)	Priority date (day/month/year) 31 January 2022 (31.01.2022)	
International Patent Classification (IPC) or both national classification and IPC IPC - INV. A61M 1/00 (2023.01) ADD. A61B 17/22; A61M 25/00 (2023.01) CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005 ADD. A61B 2017/22078; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20			
Applicant INARI MEDICAL, INC.			

1. This opinion contains indications relating to the following items: ☒ Box No. I Basis of the opinion ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application	
2. FURTHER ACTION <i>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 46.1 bis(b) that written opinions of this International Searching Authority will not be so considered.</i> <i>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</i> <i>For further options, see Form PCT/ISA/220.</i>	

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1400, Alexandria, Virginia 22313-1400 Facsimile No. 871-273-8300	Date of completion of this opinion 24 April 2023 (24.04.2023)	Authorized officer Shane Thomas PCT Help Desk Telephone No. 871-272-4300
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Form PCT/ISA/237 (cover sheet) (July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61258

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(s) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

- a. ☐ forming part of the international application as filed.
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(e)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US23/61256

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-24	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 7-10, 15, and 17-21 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics, Inc. US 2016/0030706 A1 (AngioDynamics).

As to claim 1, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4).

As to claim 2, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove extends from the distal terminus to the proximal terminus (para [0036]; claim 3).

As to claim 3, AngioDynamics teaches the aspiration catheter of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009], para [0030]).

As to claim 7, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove has a spiral shape (abstract; para [0009], para [0030]).

As to claim 8, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove comprises a plurality of grooves (fig. 4; abstract; para [0009]; para [0030]).

As to claim 9, AngioDynamics teaches the aspiration catheter of claim 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 10, AngioDynamics teaches the aspiration catheter of claim 8 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (para [0036]; claim 3).

As to claim 15, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen extending along a longitudinal axis (para [0009]), wherein the inner surface includes a plurality of grooves formed therein (channels 33), wherein the grooves extend at least partially between the distal terminus and the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus (abstract; para [0009], para [0030]).

As to claim 17, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 18, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend to the distal terminus (para [0036]; claim 3).

As to claim 19, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend entirely between the distal terminus and proximal terminus (para [0036]; claim 3).

As to claim 20, AngioDynamics teaches a system for removing material from within a lumen of a human patient, the system comprising: an aspiration catheter (30) configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4); a tubing assembly fluidly coupled to the catheter (connected to a port or syringe; para [0038], [0039]) and including a fluid control device (power aspiration para [0008] or syringe 110); and a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure (power aspiration para [0008] or syringe 110, para [0039]), wherein the fluid control device is moveable

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Supplemental Box

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between (a) a first position in which the pressure source is fluidly connected to the aspiration catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter (the catheter is fully capable of being connected and disconnected from pressure source).

As to claim 21, AngioDynamics teaches the system of claim 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves (fig. 4), wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b), wherein the grooves extend at least partially from the distal terminus to the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0008], para [0030]).

Claims 22-24 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics US 2016/0135829 A1 (AngioDynamics2).

As to claim 22, AngioDynamics2 teaches a method for removing material from within a lumen of a human patient, the method comprising: positioning a distal portion of an aspiration catheter proximate to the material within the lumen (figs. 2a-4c), wherein the aspiration catheter includes an inner surface having at least one groove formed therein (para [0037]), and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter (para [0037]); coupling a pressure source to the aspiration catheter via a fluid control device (para [0048]), wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter; activating the pressure source to generate a vacuum while the fluid control device is closed; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter (it is well known that powering on a vacuum pump will operate/activate will connect a vacuum, and powering off the pump will close/disconnect a vacuum).

As to claim 23, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter (channels form paths).

As to claim 24, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter (para [0037], [0039]; fig. 7)).

Claims 4-6, 11-13, and 16 lack an inventive step under PCT Article 33(3) as being obvious over AngioDynamics.

As to claims 4-6, AngioDynamics teaches the aspiration catheter of claim 3. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 11-13, AngioDynamics teaches the aspiration catheter of claim 10. It should be noted that AngioDynamics fails to specifically teach the plurality of grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 16, AngioDynamics teaches the aspiration catheter of claim 15. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves between about 0.13-0.15 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.13-0.15 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.13-0.15 times per inch depending on the desired effect during a procedure (para [0035]).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over AngioDynamics in view of Eskridge et al. US 2006/0264805 A1 (Eskridge).

As to claim 14, AngioDynamics teaches the aspiration catheter of claim 1. It should be noted that AngioDynamics fail to teaches wherein the catheter further comprises: an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner; a braid of wires over the inner liner; a wire coiled over the inner liner; and an outer sheath over the braid, the wire, and the inner liner. AngioDynamics does teach the desire to prevent pinching or collapsing of the catheter when negative pressure is applied (para [0007]).

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Eskridge teaches multi-layered catheter construction is well known in the art, and it is well known to combinations of liners, coils, and braids to prevent kinks (para [0005], [0027]). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of AngioDynamics to include the liner, coil, and braid of Eskridge to prevent pinching or collapsing of the catheter by increasing stiffness while still providing flexibility (para [0005], [0027]).

Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

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(54) Title: ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

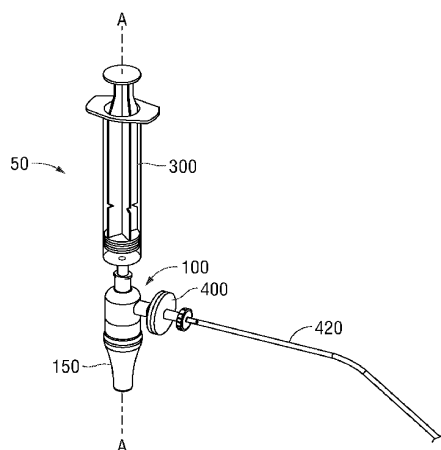


FIG. 1

(57) Abstract: A bone dust collection device includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust. The aperture extends proximally and includes a filtration member disposed therein. The filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure enables removal of bone dust collected therein. A method of collecting an anatomical specimen includes generating an anatomical specimen in particulate form at a surgical site of a subject; collecting the particulate accumulated in the collection device; and packing the collected particulate into a region of interest in the subject.

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ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to, and benefit of, U.S. Provisional Patent Application No. 62/028,552 filed on July 24, 2015, entitled "ANATOMICAL SPECIMEN COLLECTION DEVICE AND SYSTEM", by John M. Abrahams and to U.S. Provisional Patent Application No. 62/030,882 filed on July 30, 2015 of the same title, by John M. Abrahams et al., the entire contents of both of which are incorporated herein by reference.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure relates to anatomical specimen collectors.

[0004] 2. Discussion of Related Art

[0005] During orthopaedic surgery, bone is drilled and bone dust is formed. During the surgical procedure, bone replacement is performed by harvesting bone dust from a subject other than the patient or subject in the form of allograft. In addition to the expense of supplying bone replacement from a source other than the patient or subject, the equipment used for such procedures is bulky and difficult to work with.

SUMMARY

[0006] The present disclosure relates to novel and non-obvious device, system and method for harvesting an anatomical specimen such as bone dust from a subject and replacing the anatomical specimen in the subject.

[0007] More particularly, the present disclosure relates to a bone dust collection device that includes a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end. The bone dust collection structure has a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein. The filtration member is configured and disposed wherein the filtration member causes at least partial separation of fluid from the

bone dust via the fluid passing proximally through the filtration member. The bone dust collection structure is configured to enable removal of bone dust collected therein.

[0008] In one embodiment, at least one aperture may be defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough. A flow interruption member may be configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[0009] In one embodiment, least another aperture may be defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

[00010] In one embodiment, the bone dust collection device may further include a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.

[00011] In one embodiment, advancement of the plunger may cause the flow interruption member to interrupt flow from the bone dust collection structure. The bone dust collection device may further include a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.

[00012] In one embodiment, the conduit may be structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.

[00013] In still a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[00014] In a further embodiment, the bone dust collection device may further include another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system. and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

[00015] In yet another embodiment, the bone dust collection device may further include a bone dust removal structure defining an aperture having a proximal end and a distal end. The aperture may be configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.

[00016] In a still further embodiment, the bone dust removal structure may include a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure. In yet another embodiment, the nozzle may be removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

[00017] In one embodiment, the bone dust collection device may further include a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.

[00018] In one embodiment, the flow interruption member may be an umbrella valve. In yet another embodiment, the another flow interruption member is a check valve.

[00019] The present disclosure relates also to a bone dust collection device that includes a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

[00020] The present disclosure relates also to an anatomical collection system that includes an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure. The anatomical specimen removal

structure is removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

[00021] In one embodiment, the anatomical specimen is bone dust.

[00022] The present disclosure relates also to a method of collecting an anatomical specimen that includes generating an anatomical specimen in particulate form at a surgical site of a subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing a tip of a collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00023] The method may further include packing the collected particulate into a region of interest in the subject.

[00024] In one embodiment, the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, and the method may further include reassembling the collection device; generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[00025] The method may further include packing the additionally collected particulate into a region of interest in the subject.

[00026] In one embodiment, the aspirating of the collection device may include connecting the collection device to a vacuum source, which in one embodiment, may be in an operating room, wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.

[00027] In one embodiment, the aspirating of the collection device may include actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

BRIEF DESCRIPTION OF THE DRAWINGS

[00028] The advantages of the embodiments of the present disclosure will become apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:

[00029] FIG. 1 is a transparent perspective view of a bone dust collection system according to one embodiment of the present disclosure;

[00030] FIG. 2 is an exploded view of a bone dust collection device that is included within the bone dust collection system of FIG. 1;

[00031] FIG. 3 is a profile view of one embodiment of a bone dust collection device that may be included within the bone dust collection system of FIG. 1;

[00032] FIG. 4 is a partial profile cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having one embodiment of a filtration member according to the present disclosure;

[00033] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure of the bone dust collection device of FIG. 3 having an embodiment of a filtration member according to the present disclosure;

[00034] FIG. 6A is an end view of a filter that is included within the bone dust collection device of FIGS. 1-5;

[00035] FIG. 6B is a side view of the filter of FIG. 6A;

[00036] FIG. 6C is a view of Detail 6C of FIG. 6B;

[00037] FIG. 6D is a proximal perspective view of the filter of FIGS. 6A-6C;

[00038] FIG. 7A is an end view of one embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;

[00039] FIG. 7B is a cross-sectional view of the nozzle of FIG. 7A taken along cross-section line 7B-7B;

- [00040] FIG. 8A is an end view of another embodiment of a nozzle that may be included within the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00041] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B;
- [00042] FIG. 9A is an end view of one embodiment of a valve cap that that may be included with the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00043] FIG. 9B is a cross-sectional view of the valve cap of FIG. 9A taken along section line 9B-9B;
- [00044] FIG. 10 is an exploded partially transparent view of a handle assembly that may be included as part of the bone dust collection device of the bone dust collection system of FIGS. 1-5;
- [00045] FIG. 10A is a cross-sectional view of the handle assembly of FIG. 10;
- [00046] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal;
- [00047] FIG. 12 is a perspective, partially transparent view of the handle assembly of FIG. 11 and the bone dust collection device of FIGS. 1-2 and 4-5 that includes a check valve seal;
- [00048] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure that includes a check valve and a flow diversion member for diverting fluid flow from the bone dust collection device;
- [00049] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13;
- [00050] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection system of FIG. 1-3;
- [00051] FIG. 15A is a detailed view of an extraction flow interruption member illustrated in the form of an umbrella valve that is positioned on an upper surface of the housing in a closed position;

- [00052] FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface of the housing in an open position to enable flow of fluid past the umbrella valve;
- [00053] FIG. 16 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position as illustrated in FIG. 15A;
- [00054] FIG. 17 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the open position for permitting passage of fluid past the umbrella valve;
- [00055] FIG. 18 is a cross-sectional view of the bone dust collection device when the umbrella valve is in the closed position for discharging and diverting fluid which has been collected by syringe;
- [00056] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device having the alternate filtration member shown in FIG. 4 and wherein the umbrella valve is in the open position;
- [00057] FIG. 20 is cross-sectional view of the bone dust collection device of FIG. 19 wherein the umbrella valve is in the closed position and fluid is diverted through a check valve;
- [00058] FIG. 21 is a cross-sectional view of the bone dust collection device having the filtration member of FIG. 5 in an inverted position to allow removal of collected bone dust;
- [00059] FIG. 22 is a cross-sectional view of the bone dust collection device of FIG. 19 in an inverted position to allow removal of collected bone dust;
- [00060] FIG. 23 is a perspective transparent view of a kit package that houses bone dust collection devices according to embodiments of the present disclosure;
- [00061] FIG. 24 is a perspective view of the bone dust collection device of FIG. 3 having a plug member to seal off flow during connection of the bone dust collection device to a continuous vacuum system;
- [00062] FIG. 25 is a perspective view of the bone dust collection device of FIGS. 1-2 and 4-5 having a fluid flow diversion member and a check valve wherein fluid flow is directed vertically downward;

- [00063] FIG. 26 is a cross-sectional view of the bone dust collection device of FIG. 25;
- [00064] FIG. 27 is a perspective view of the bone dust collection device of FIGS. 25 and 26 wherein the fluid flow is directed horizontally;
- [00065] FIG. 28 is a perspective view of the bone dust collection device of FIG. 24 wherein the plug member is replaced by a flow diversion member to enable diversion of fluid back to a surgical site;
- [00066] FIG. 29 is a transparent elevation view of the bone dust collection device of FIG. 28;
- [00067] FIG. 30 is a perspective view of the bone dust collection device of FIG. 28 wherein a tubular portion of the flow diversion member has been removed;
- [00068] FIG. 31 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in an alternative direction with respect to a surgical site; and
- [00069] FIG. 32 is a perspective view of the bone dust collection device of FIG. 30 wherein the flow diversion member is oriented at an angle to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

DETAILED DESCRIPTION

- [00070] To advance the state of the art of bone dust collection, the present disclosure relates to a bone dust collection system where a user, e.g., a surgeon or other medical professional, is able to simply collect bone dust using a hand-held device during aspiration from a surgical site.
- [00071] As defined herein, a bone dust collection device refers to an assembly of components which may either be employed independently or in a self-contained manner to collect bone dust while a bone dust collection system refers to utilization of the device and its assembly of components in conjunction with an external suction source such as via fluid communication with an operating room suction or vacuum system. The suction or vacuum system may also be located outside of an operating room under appropriately certified conditions. The device can be used to collect other anatomical specimen besides bone dust, such as, for example, bone marrow or other biological cells.

[00072] The bone dust collection device enables collection of bone dust, defined herein as generally in the range of about 25 micron to about 600 micron cross-section bone particles, during a surgical procedure in order to harvest and use the bone dust for bone fusion mass in orthopedic surgery of the same patient. In actuality, the bone dust collection device enables collection of bone dust of sizes generally known to be created during surgical procedures.

[00073] The device generally may be applied to one or more medical procedures performed on a single patient. The device may be utilized as a stand-alone bone collection device that includes a syringe or the device may be adapted as a bone collection system by fluidically coupling the device to a vacuum source such as commonly found in an operating room environment. The device may be used multiple times on the same patient during the same operating procedure but is discarded after completion of usage.

[00074] The output of the device may be a “plug” of bone that can be held with forceps and placed into an intervertebral cage or used for any other procedure that requires bone or fusion construct. The output of the device may also be bone dust that is concentrated and can be manually placed into an intervertebral cage or construct or placed therein using instruments.

[00075] The device is configured to allow fluids, e.g., blood and saline, to pass through a separator or filtration member, .e.g., a filter or a valve mechanism, thus separating bone dust from fluids. The bone dust collection device aspirates surgical fluid and filters out bone dust for use during a surgical procedure.

[00076] The bone dust so collected may be processed by the user during the procedure wherein the processing of the bone dust may include cleaning, compacting, and transfer of the bone dust.

[00077] As described above, the bone dust collection device may be disposed of, and in most cases is intended to be discarded, following usage.

[00078] After using a surgical drill, the user aspirates surgical fluid to filter and then harvest bone dust; Fluid is discarded and bone dust is removed from a collection chamber defined within the bone dust collection device. Bone dust may be used for fusion or reconstruction procedures. Procedures include, but are not limited

to, e.g., spinal fusion, long bone fusion, cranial reconstruction, craniofacial reconstruction, orthopaedic reconstruction, or dental reconstruction.

[00079] Turning now to FIGS. 1, 2 and 3, there is illustrated a bone dust collection system 50 that includes a bone dust collection device according to one embodiment of the present disclosure. More particularly, bone dust collection device 100 includes a cylindrically-shaped bone dust collection structure 110 that extends from a proximal end 114a to a distal end 114b of the bone dust collection structure 110. The proximal end 114a of the bone dust collection structure 110 is configured as a valve support plate 116 such that the bone dust collection structure 110 also serves as a valve support structure. Cylindrical wall 118 extends distally from the valve support plate 116 to define a central aperture and volume 120 for receiving and collecting bone dust (see FIG. 3).

[00080] As best illustrated in FIG. 2 and FIG. 3, the valve support structure or bone dust collection structure 110 includes a valve supporting surface or plate 116 near the proximal end 114a.

[00081] The central aperture 120 extends proximally towards proximal end 114a of the bone dust collection structure 110 and includes a filtration member 122 disposed therein that may be part of a filter assembly 124. The filter assembly 124 may include a ring-shaped filter mounting member 126 that is configured to be disposed within the central aperture 120.

[00082] As explained in more detail below, the filtration member 122 and the filter assembly 124 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. Thus, the bone dust collection structure 110 is configured to enable removal of bone dust collected therein.

[00083] As best shown in FIG. 2, the bone dust collection device 100 defines a central longitudinal axis **A-A** that extends from a proximal end 100a to a distal end 100b. At least one fluid flow aperture 116a is defined in the transverse plate member 116 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. A fluid extraction valve shaft aperture 116' is also defined in the transverse plate member 116 generally

through the center **C** of the transverse plate member 116 through which longitudinal axis **A-A** passes. A second fluid flow aperture 116b may also be defined in the transverse plate member 116 on a side of the longitudinal axis **A-A** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 116a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted also that the bone dust collection structure 110 may be oriented such that the first and second fluid flow apertures 116a and 116b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 116a and 116b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 100.

[00084] The bone dust collection device 100 further includes a fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 110 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 116a and 116b, of the bone dust collection structure 110 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 116a and 116b.

[00085] As indicated above, fluid extraction valve shaft aperture 116' is defined in the transverse plate member 116. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes a shaft member 132 that is disposed through the fluid extraction valve shaft aperture 116'. The extraction flow interruption member 130 includes a diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side of transverse plate member 116 such that the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and

more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow through the apertures 116a and 116b. The shaft member 132 includes a proximal portion 132a and a distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. The fluid extraction valve shaft aperture 116' is thus shaped accordingly to define a proximal narrow diameter portion and a distal wide diameter portion to match the proximal and distal portions 132a and 132b of the shaft member 132.

[00086] In the embodiment of the housing 110 illustrated in FIG. 3, a portion 1161 of the transverse plate member 116 extends distally into the central aperture 120 to define a circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116. The filter assembly 124 is configured and disposed wherein the ring-shaped filter mounting member 126 is received in the circumferential channel 136 such that the filtration member 122 overlays the distal ends of the fluid flow apertures 116a and 116b.

[00087] The bone dust collection device 100 may further include a bone dust removal structure 150 that defines an aperture 152 having a proximal end 152a and a distal end 152b. In one embodiment, the bone dust removal structure 150 may include, or be formed in the shape of, a nozzle wherein proximal end 154a of the nozzle 150 may engage with outer surface 118b of housing wall 118 for structural stability of the nozzle 150 during usage for collecting bone dust. The aperture 152 of the nozzle 150 is configured and disposed for facilitating transport of bone dust, or a mixture of bone dust and irrigating fluid such as saline solution, as represented by arrow **B**, from the distal end 152b of the bone dust removal structure or nozzle 150 to the central aperture 120 of the bone dust collection structure 110. When in the form of a nozzle, the nozzle thus defines the aperture 152 of the bone dust removal structure 150. The nozzle defines the proximal end 152a and distal end 152b, wherein the nozzle facilitates transport of the bone dust **B**, which includes fluid from the surgical site, to the bone dust

collection structure 110. The nozzle may be removably attached to the bone dust collection structure 110 by disengaging from outer surface 118b of housing wall 118. Removal of the nozzle 150 from the bone dust collection structure 110 enables removal of bone dust collected within the bone dust collection structure 110, as described in more detail below. The nozzle 150 may be made from flexible, elastomeric materials, such as, but not limited to, silicone or urethane.

[00088] The bone dust collection device 100 may further include a tee-shaped port member or cap 160 that defines a bone dust collection interface aperture 162b at a distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define a suction device interface aperture 162a at a proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines a fluid diversion aperture 162c at branch connection 160c. As described in more detail below, when in operation, the bone dust collection device 100 in FIG. 3 is connected to a continuous suction source, such as an operating room suction system, at suction device interface aperture 162a. When in this mode of operation for collecting bone dust, the fluid diversion aperture 162c is sealed via a plug 164 inserted therethrough. Fluid from the surgical site is separated from the bone dust (arrow **B**) by the filtration member 122 and passes through to the suction device interface aperture 162a. Suction is maintained by the presence of the plug 164.

[00089] FIG. 4 is a cross-sectional view of the bone dust collection system of FIGS. 1 and 2 having another embodiment of a bone dust collection device according to the present disclosure. More particularly, bone dust collection system 50' is identical to bone dust collection system 50 except that bone dust collection structure 110 is replaced by bone dust collection structure 210 which differs from bone dust collection structure 110. For simplicity, only those features of bone dust collection structure 210 which differ from the corresponding features of bone dust collection structure 110 are described. Additionally, those features are numbered as 210 instead of 110, 216 instead of 116, etc. Reference to FIG. 3 is implied where features not explicitly shown in FIG. 4 are described.

[00090] Bone dust collection device 200 includes cylindrically-shaped bone dust collection structure 210 that extends from proximal end 214a to distal end 214b of the bone dust collection structure 210. The proximal end 214a of the bone dust collection structure 210 is also configured as a valve support plate 216 such that the bone dust collection structure 210 also serves as a valve support structure in the same manner as described above with respect to bone dust collection device 100. Cylindrical wall 118 extends distally from the valve support plate 216 to define a central aperture and volume 220 for receiving and collecting bone dust.

[00091] Valve support structure or bone dust collection structure 210 includes valve supporting surface or plate 216 near the proximal end 214a.

[00092] The central aperture 220 extends proximally towards proximal end 214a of the bone dust collection structure 210 and includes filtration member 122 disposed therein that may be part of filter assembly 224. The filter assembly 224 may now include ring-shaped filter mounting member 226 that is configured to be disposed within the central aperture 220.

[00093] Again, as explained in more detail below, the filtration member 122 and the filter assembly 224 are configured and disposed wherein the filtration member 122 causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member 122. The filter assembly 224 and filtration member 122 are mounted within the central aperture 220 wherein the ring-shaped filter mounting member 226 has an outside diameter approximately corresponding to the inside diameter of the cylindrical wall 118 such that the ring-shaped filter mounting member 226 may be disposed in a snug fit within the bone dust collection structure 210. Thus, the bone dust collection structure 210 is also configured to enable removal of bone dust collected therein.

[00094] Although illustrated as an assembly of filtration member 122 and the filter mounting member 226, the filter assembly 224 may be a molded construction. In either case, the filtration member 122 may be a mesh with an over-under weave knit material or be a molded membrane with small holes or apertures formed therein, on the order of 100 microns (μm) in cross-sectional distance. The

filtration member 122 may be made from, but not limited to, materials such as fiberglass, copper or stainless steel. The ring-shaped filter mounting member 226 may be made from a thermoplastic elastomer such as polyvinyl chloride and urethane.

[00095] Bone dust collection device 200 also defines a central longitudinal axis **A'-A'** that extends from proximal end 100a to distal end 100b. At least one fluid flow aperture 216a is defined in transverse plate member 216 that enables the fluid at least partially separated from the bone dust by the filtration member 122 to pass therethrough. Fluid extraction valve shaft aperture 216' is also defined in the transverse plate member 216 generally through the center **C** of the transverse plate member 216 through which longitudinal axis **A'-A'** passes. Second fluid flow aperture 216b may also be defined in the transverse plate member 216 again on a side of the longitudinal axis **A'-A'** opposite to the first fluid flow, e.g., at a position 180° from the first fluid flow aperture 216a, which is at position 0°. Additional fluid flow apertures (not shown) may also be positioned at 90° or 270° or other suitable locations if desired. It should be noted again that the bone dust collection structure 210 may also be oriented such that the first and second fluid flow apertures 216a and 216b may coincide with the 90° and 270° positions, respectively, or vice versa. Such interchangeability of the orientation of the first and second fluid flow apertures 216a and 216b is taken advantage of throughout the description which follows where necessary or desirable to explain the operation of the bone dust collection device 200.

[00096] The bone dust collection device 200 further includes also fluid extraction flow interruption member 130 that is configured and disposed with respect to the bone dust collection structure 210 wherein, as explained in more detail below, flow of fluid through at least one aperture or, for example, fluid flow apertures 216a and 216b, of the bone dust collection structure 210 occurs by suction pressure induced on the fluid extraction flow interruption member 130 causing the flow interruption member 130 to change position to enable flow through fluid flow apertures 216a and 216b.

[00097] As indicated above, fluid extraction valve shaft aperture 216' is defined in the transverse plate member 216. As shown in FIG. 3, the extraction flow interruption member 130 may be an umbrella valve as shown and which includes shaft member 132 that is disposed through the fluid extraction valve shaft aperture 216'. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 216a and 216b on the proximal side of transverse plate member 216. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 216 to expose the fluid flow apertures 216a and 216b, thereby enabling flow through the apertures 216a and 216b. The shaft member 132 includes again proximal portion 132a and distal portion 132b wherein the distal portion 132b defines a diameter that is greater than the diameter of the proximal portion 132a. However, in contrast to fluid extraction valve shaft aperture 116', fluid extraction valve shaft aperture 216' is thus shaped accordingly to define a narrow diameter portion to match the proximal portion 132a of the shaft member 132. The transverse plate member 216 is not characterized by the portion 1161 of the transverse plate member 116 that extends distally into the central aperture 120. Thus there is no circumferential channel 136 between inner surface 118a of the housing wall 118 and the distally extending portion 1161 of the transverse plate member 116.

[00098] The bone dust collection device 200 also includes the bone dust removal structure 150 mounted on cylindrical wall 118 and tee-shaped port member or cap 160 mounted to bone dust collection structure 210 at proximal end 214a in a similar manner as described above with respect to FIG. 3. However, a suction device 300 is now inserted into the suction device interface aperture 162a while a fluid flow diversion interruption device 400 is in fluid communication with fluid diversion aperture 162c at branch connection 160c.

[00099] Fluid flow diversion interruption device 400 is configured and disposed with respect to the flow interruption member 130 and with respect to the bone dust collection structure 210 wherein suction pressure induced on the flow interruption member 130 causes the flow interruption member 130 to change position to enable flow through the apertures 216a and 216b defined in the transverse plate member 216 while fluid flow diversion interruption device 400 is in a closed position.

[000100] In one embodiment, suction device 300 may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 210 via distal port 302b of the syringe 302 inserted into the suction device interface aperture 162a of tee-shaped port member or cap 160. Suction pressure is caused by retraction of the plunger 304 in the proximal direction away from the bone dust collection structure 210 to enable flow through the apertures 216a and 216b defined in the transverse plate member 216.

[000101] Conversely, advancement of the plunger 304 distally causes the flow interruption member 130 to interrupt flow from the bone dust collection structure 210 while fluid is diverted through the fluid flow diversion interruption device 400 which includes an upstream port 400a that is inserted in fluid diversion aperture 162c of the tee-shaped port member or cap 160.

[000102] On downstream side 400b of fluid flow diversion interruption device 400, there is disposed a conduit 410 in fluid communication with the bone dust collection structure 210, wherein advancement of the plunger 304 causes the fluid (as represented by arrow **F**) received through the apertures 216a and 216b defined in the transverse plate member 216 to discharge through the fluid conduit 410 away from the bone dust collection device 200 in the direction of arrow **F**. Fluid communication between the fluid conduit 410 and the fluid flow diversion interruption device 400 may be established via a luer valve 412 connecting the fluid conduit 410 to the downstream side 400b. In one embodiment, the fluid flow diversion interruption device 400 may be a check valve installed so as to enable flow of fluid in the direction of arrow **F** and to prevent flow in the direction opposite to arrow **F**. In one embodiment, the conduit 410 is structured such that

the conduit 410 discharges the fluid in a direction generally perpendicular, e.g., in the direction of arrow **F**, to the direction of fluid flow through the filtration member 122.

[000103] FIG. 5 is a cross-sectional enlarged view of the bone dust collection housing and valve support structure 110 of the bone dust collection device of FIG. 3 having an embodiment of the filtration member 122 and transverse plate member 116 with circumferential channel 136 described above with respect to FIG. 3.

[000104] FIG. 6A is an end view of the filter assembly 124 that is included within the bone dust collection device 200 of FIGS. 1-3 and 5. FIG. 6B is a side view of the filter assembly 124 of FIG. 6B illustrating wherein ring-shaped filter mounting member 126 includes a cylindrical wall 128 which is configured and disposed to be received within the circumferential channel 136 illustrated in FIGS. 3 and 5. The cylindrical wall 128 has a height dimension **H** above the filtration member 122. The cylindrical wall 128 may be characterized by a partially contoured profile at the proximal end having a radius of curvature **R**. The ring-shaped filter mounting member 126 may define an inner diameter **D1** and an outer diameter **D2**.

[000105] FIG. 6C is a view of Detail 6C of FIG. 6B wherein ring-shaped filter mounting member 126 includes cylindrical wall 128.

[000106] FIG. 6D is a proximal perspective view of the filter assembly 124 of FIGS. 6A-6C.

[000107] FIG. 7A is an end view of the bone dust removal structure 150 in the form of a nozzle that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000108] FIG. 7B is a cross-sectional view of the nozzle 150 of FIG. 7A taken along cross-section line 7B-7B. The diameter **D3** of central aperture 152 at proximal end 152a tapers in the distal direction to diameter **D4** at distal end 152b such that diameter **D3** is greater than diameter **D4**. Having the tapered configuration such that the diameter of the central aperture 152 increases from the distal end 152b

to the proximal end 152a tends to minimize flow obstruction during operation of the bone collection device 100.

[000109] FIG. 8A is an end view of another embodiment of bone dust removal structure in the form of a nozzle 250 that may be included within the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000110] FIG. 8B is a cross-sectional view of the nozzle of FIG. 8A taken along cross-section line 8B-8B. More particularly, nozzle 250 defines a generally constant diameter D5 circular aperture 251 at proximal end 250a wherein the circular aperture 251 is configured and disposed to receive the filter assembly 124 (see FIG. 1-5). Nozzle 250 further defines another generally constant diameter D6 circular aperture 252 that extends distally from an interface 254 with circular aperture 251 wherein bone dust B is suctioned from distal end 250b. In a similar manner as with respect to nozzle 150, nozzle 250 may be made from flexible, elastomeric materials, such as, but not limited to, silicone.

[000111] FIG. 9A is an end view of one embodiment of valve tee-shaped port member or cap 160 that that may be included with the bone dust collection device 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5.

[000112] FIG. 9B is a cross-sectional view of the valve cap tee-shaped port member or cap 160 of FIG. 9A taken along section line 9B-9B.

[000113] As described above with respect to FIG. 4, tee-shaped port member or cap 160 that defines bone dust collection interface aperture 162b at distal portion 160b of the tee-shaped port member or cap 160. The tee-shaped port member or cap 160 may further define suction device interface aperture 162a at proximal portion 160a. Additionally, tee-shaped port member or cap 160 defines fluid diversion aperture 162c at branch connection 160c at generally a right angle with respect to interface apertures 162a and 162b.

[000114] FIG. 10 is an exploded partially transparent view of a handle assembly 500 that may be included as part of the bone dust collection devices 100 or 200 of the bone dust collection systems 50 or 50' of FIGS. 1-5. The handle assembly 500 includes a central handle member 502 having a generally cylindrical

configuration with a knurled outer surface 502a having a series of ridges to assist a user in gripping the handle member 502. The central handle member 502 also defines a central bore or aperture 504 that extends from proximal end 506a of the handle member 502 to distal end 506b of the handle member 502.

[000115] The handle assembly 502 may further include a connector member 510 at proximal end 506a. The connector member 510 defines a barbed proximal end 512a and a barbed distal end 512b and a central bore 514 extending through each end. Distal barbed end 512b of connector member 510 is configured and disposed to engage with proximal end 506a of the central handle member 502 and be received within the central bore or aperture 504.

[000116] Additionally, the handle assembly 500 may include at distal end 506a of central handle member 502 a luer fitting 516 having a proximal barbed end 518a. The luer fitting 516 defines a central bore 520 such that the proximal barbed end 518a is configured to be received within the central bore or aperture 504.

[000117] FIG. 10A is a cross-sectional view of the handle assembly 500 of FIG. 10.

[000118] FIG. 11 is a perspective, partially transparent view of the handle assembly of FIGS. 10 and 10A and the bone dust collection device of FIG. 3 that includes a plug seal forming a bone dust collection system 600. As can be appreciated by the foregoing description of FIGS. 110 and 10A, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S**. The fluid extraction flow interruption member 130 (see FIG. 3) is now in an open position to permit the passage of fluid through the handle assembly 500 while

fluid flow through the fluid diversion aperture 162c at branch connection 160c is sealed via the plug member 164. Bone dust is collected in the bone dust collection device 100 or 200.

[000119] FIG. 12 is a transparent view of the handle assembly 500 of FIG. 11 and the bone dust collection device 100 or 200 of FIGS. 1-5 forming bone dust collection system 600'. As can be appreciated by the foregoing description of FIG. 11, when the handle assembly 500 is assembled as shown wherein the luer fitting 516, the central handle member 502 and the connector member 510 are connected in series, fluid communication is again established from the luer fitting 516 to the connector member 510 via the central bore 520 of the luer fitting 516, the central bore 504 of the central handle member 502 and the central bore 514 of the connector member 510. In this configuration, suction is again established through the handle assembly 500 in the proximal direction of arrow **S** by connection to a continuous suction source such as an operating room such system (not shown). Bone dust as represented by arrow **B** at bone dust removal structure 150 is collected by the bone dust collection device 100 or 200 by the establishment of the suction condition **S**. The fluid extraction flow interruption member 130 (see FIG. 3) again is now in an open position to permit the passage of fluid through the handle assembly 500 while, in contrast to the sealing provided by plug member 164, the fluid flow diversion interruption device 400 is in a closed position. Bone dust is collected in the bone dust collection device 110 or 210.

[000120] FIG. 13 is a partially transparent view of one embodiment of a self-contained bone dust collection device according to the present disclosure. More particularly, referring to FIG. 4 above, self-contained bone dust collection device 700 includes the suction device 300 which may be a syringe 302 including a plunger 304 in fluid communication with the bone dust collection structure 110 (see FIG. 3) or bone dust collection structure 210. However, as described above with respect to FIG. 5, in lieu of fluid conduit 410, self-contained bone collection device 700 includes flow diversion member 420 that is in fluid communication with the fluid flow diversion interruption device 400 on the downstream side 400b.

[000121] Again, flow diversion member 420 may be a right angle or 90 degree luer valve and is further described below. When the plunger 304 is advanced distally following retraction and accumulation of fluid within the syringe 302, fluid flow diversion interruption device 400 shifts to the open position (while fluid extraction flow interruption member 130 shifts to the closed position) to divert fluid through flow diversion member 420. Flow diversion member 420 may be utilized to divert fluid back to a surgical site by directing the fluid vertically downward as shown by arrow **F1**.

[000122] FIG. 13A is a partially transparent view of another embodiment of the self-contained bone collection device of FIG. 13. More particularly, bone dust collection device 700' differs from bone dust collection device 700 in that fluid flow diversion interruption device 400 is now downstream of flow diversion member 420.

[000123] FIG. 14 is a zoomed out partial profile cross-sectional view of the bone dust collection systems 50 or 50' that includes fluid conduit 410 of FIG. 1-3. FIG. 15A is a detailed view of extraction flow interruption member 130 illustrated in the form of umbrella valve 130 that is positioned on upper surface 115 of the housing in a closed position. The extraction flow interruption member 130 again includes diaphragm 134 that is formed with the shaft member 132. The diaphragm 134 is again made from an elastomeric and flexible material and which overlays the fluid flow apertures 116a and 116b on the proximal side or upper surface 115 of transverse plate member 116. FIG. 15B is a detailed view of the umbrella valve positioned on the upper surface 115 of the housing in an open position to enable flow of fluid past the umbrella valve. Again, the change of position of the extraction flow interruption member 130 occurs via the suction pressure induced on the flow interruption member, and more particularly on the diaphragm 134, such that the diaphragm 134 flips away from the transverse plate member 116 to expose the fluid flow apertures 116a and 116b, thereby enabling flow of fluid through the apertures 116a and 116b, as indicated by arrows F2A and F2B, respectively. Those skilled in the art will recognize that the actual flexing and flipping of the diaphragm 134 to establish the open position is a very

small rise away from the transverse plate member 116. That is, the diaphragm 134 must flex upwardly sufficiently to enable passage of the fluid, such as blood and/or saline solution, with any particulates including bone dust or other anatomical specimens contained therein that have passed through the filtration member 124 (see FIG. 3) while the anatomical specimen is being collected. The umbrella valve may be made from thermoplastic elastomers such as, but not limited to, polyvinyl chloride or urethane or the like.

[000124] FIG. 16 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position as described above with respect to FIG. 15A.

[000125] FIG. 17 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the open position for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**. In this configuration, the suction device 300 which may be in the form of syringe 302 as described above draws suction on the interface aperture 162a to enable the fluid to be drawn into the syringe. During this operation, the plunger 304 is retracted proximally through the syringe 302.

[000126] FIG. 18 is a cross-sectional view of the bone dust collection device 100 or 200 when the umbrella valve 130 is in the closed position for discharging and diverting fluid which has been collected by syringe 302 in the direction of arrow **F4** through fluid diversion aperture 162c at branch connection 160c. During this operation, the plunger 304 is advanced distally through the syringe 302.

[000127] FIG. 19 is a cross-sectional view of another embodiment of the bone dust collection device 200 having the alternate filtration member 224 shown in FIG. 4. During this operation, the fluid flow diversion interruption device 400 is in the closed position and the umbrella valve 130 is in the open position. for permitting passage of fluid past the umbrella valve 130 as shown by arrows **F2A** and **F2B** and then through suction device interface aperture 162a at proximal portion 160a as shown by arrow **F3**.

[000128] FIG. 20 is cross-sectional view of the bone dust collection device 200 of FIG. 19 wherein the umbrella valve 130 is in the closed position and fluid is diverted through fluid diversion aperture 162c and the fluid flow diversion interruption device 400 in the direction of arrow **F4**.

[000129] Although the flow interruption member 130 has been illustrated as an umbrella valve, other flow interruption members may be employed such as a miter valve or duck bill valve, a check or flapper valve, or a disk valve or the like. In such cases, the tee-shaped port member or cap 160 and/or the filtration assembly 224 may be reconfigured if or as necessary to accommodate the design, operation and configuration of the particular flow interruption member being employed.

[000130] FIG. 21 is a cross-sectional view of the bone dust collection device 100 having the filtration member 124 of FIG. 5 in an inverted position to allow removal of collected bone dust 180. The collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000131] FIG. 22 is a cross-sectional view of the bone dust collection device 200 of FIG. 19 in an inverted position to allow removal of collected bone dust 180. Similarly, the collected bone dust 180 may be removed manually with a flat instrument or spatula or by a power-assisted instrument including a suction source.

[000132] FIG. 23 is a perspective transparent view of a kit package 800 that houses the bone dust collection devices 100 or 200 and associated components according to embodiments of the present disclosure.

[000133] More particularly, kit 800 includes a support tray 802 that defines a first depression 804a and an adjacent second depression 804b which are interconnected via a central depression 804c. As illustrated, suction device 300 is received in first depression 804a, handle assembly 500 is received in second depression 804b together with plug member 164 while bone dust collection device 100 or 200 may be received in central depression 804c. When provided

with a covering (not shown), the kit package and contents may be provided to the user in a sterile condition via means known in the art.

[000134] Alternatively, the contents may also be provided in a sterile condition in a taped banded bag such as, for example, a Sklar banded bag product no. 96-5582 or equivalent as necessary due to the size of the contents (not shown – by Sklar Instruments, West Chester, Pennsylvania, USA) or Tyvek® (DuPont de Nemours, Inc.) pouch or equivalent as known in the art.

[000135] FIG. 24 is a perspective view of the bone dust collection device 100 of FIG. 3 having plug member 164 to seal off flow through fluid diversion aperture 162c at branch connection 160c during connection of the bone dust collection device to a continuous vacuum system.

[000136] FIG. 25 is a perspective view of the bone dust collection device 100 or 200 of FIG. 24 wherein the plug member 164 is replaced by flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000137] FIG. 26 is a cross-sectional view of the bone dust collection device 100 of FIG. 25 with fluid flow diversion member 420 in the form of a 90 degree elbow and fluid flow diversion interruption device 400 to enable diversion of fluid in a vertically downward direction back to a surgical site.

[000138] FIG. 27 is a perspective view of the bone dust collection device 100 or 200 of FIGS. 25 and 26 wherein the fluid flow is directed horizontally.

[000139] FIG. 28 is a perspective view of the bone dust collection device 100 or 200 of FIG. 25-27 wherein the fluid flow diversion interruption device 400 is replaced by a fluid port connection fitting member 430 and a tubular member 440 to enable diversion in a vertically downward direction of fluid back to a surgical site.

[000140] FIG. 29 is a cross-sectional elevation view of the bone dust collection device 100 or 200 of FIG. 28 wherein fluid port connection fitting member 430 and tubular member 440 enable diversion of fluid in a vertically downward direction.

[000141] FIG. 30 is a perspective view of the bone dust collection device 100 or 200 of FIG. 29 wherein tubular member 440 of the fluid port connection fitting member 430 has been removed.

[000142] FIG. 31 is a perspective view of the bone dust collection device 100 or 200 of FIG. 30 wherein the flow diversion member 430 is oriented at an angle of 45 degrees below the horizontal to enable diversion of fluid in an alternative direction with respect to a surgical site.

[000143] FIG. 32 is a perspective view of the bone dust collection device 100 or 200 of FIG. 28 wherein the flow diversion member 430 is oriented horizontally to enable diversion of fluid in yet another alternative direction with respect to a surgical site.

[000144] From the foregoing description, it can be appreciated that the harvested or collected bone may be used during:

[000145] (1) Fusion construct - spine or long bone - to promote fusion healing.

[000146] (2) Bone fusion wherein placement of bone dust into a fusion device such as a cage implant may be utilized to promote bone fusion.

[000147] (3) Replacement of bone after craniotomy or any skull base procedure where bone is removed.

[000148] (4) Dental reconstruction/fusion procedure.

[000149] Between the bone dust collection structure and the syringe, the one-way valve or check valve allows for continued suction and expulsion of air without disconnecting the syringe from the bone dust collection device.

[000150] The size of the central aperture and volume 120 (see FIG. 3) and 220 (see FIG. 4) for receiving and collecting bone dust can be altered depending on use of the device. The size of the bone collection devices 110 and 210 (see FIGS. 3 and 4, respectively) and respective central apertures and volumes 120 and 220 can be made smaller for cervical surgery or made larger for lumbar surgery or long bone repair.

[000151] Embodiments of the bone dust collection device may include a mechanism to include or mix bone marrow aspirate or also other biological cells.

[000152] Since bone marrow is flexible tissue, embodiments of the bone dust collection device may be used to filter bone marrow alone as a separate device and without the need for drilling. In such embodiments, the filter design parameters may be adjusted accordingly to suit collection of bone marrow or other biological cells.

[000153] The bone dust collecting structures 110 or 210 may be centrifuged to spin down bone products and separate blood products.

[000154] The harvesting or bone dust collection system or self-contained device generally is provided via a sterile cartridge, adaptable to a standard luer fitting. The harvesting system may be provided sterile by the medical device manufacturer.

[000155] The filter assembly allows blood and fluids to pass, but generally retains bone particles between about 75 to about 300 microns. Filter mesh size may be optimized, such as by empirical testing of various filter sizes and types, to result in minimal fluid flow restriction and clogging during the procedure and to result in maximal bone fragment collection. Consideration must also be given to optimization and alternate particle size ranges when collecting other anatomical specimens such as bone marrow or other biological cells.

[000156] The bone dust collection volume generally is about 0.5 cc (cubic centimeters) minimum.

[000157] The device may be designed to allow a clinician to cycle the syringe multiple times while harvesting bone dust, while dispensing blood/saline out of the side port.

[000158] The bone dust harvesting system allows easy removal of the bone dust from the device. The device allows cleaning of the bone dust using a sterile saline flush. The harvesting system allows easy consolidation and removal of the bone dust. Removal methods include utilizing a scoop (spatula, spoon or similar). Prior to removal of the bone dust, aspiration of the bone dust via air flow may assist in drying the bone dust to result in a more cohesive bone plug when removing the bone dust.

[000159] The device is generally provided sterile in a double Tyvek® pouch in order to comply with sterile transfer protocol in the sterile OR field.

[000160] Sterilization methods may include exposure to Gamma radiation.

[000161] The bone dust collection device may be reused on the same patient during the same surgical procedure. The device generally should not be re-sterilized. It is intended for use in the collection of bone dust created during a surgical procedure when using any high-speed drill that creates bone dust (cutting burrs, diamond burrs, etc.).

[000162] The device generally does not contain latex.

[000163] Bone dust collected by the surgeon is used for the procedure at his or her discretion. As indicated above, bone dust can be packed into an interbody cage device to augment a fusion construct. In conjunction with FIG. 11 or FIG. 12 and the foregoing disclosure.

[000164] TABLE 1 below indicates detailed method steps for “Using the Bone Dust Collection System with Operating Room Suction.”

TABLE 1
USING THE BONE DUST COLLECTION SYSTEM WITH OPERATING ROOM
SUCTION

Step No.	Description
1.	Open the single-pouch in a sterile fashion onto the operating room surgical field.
2.	Insert side plug into valve body of the device.
3.	Attach handle assembly to the luer lock of the device.
4.	Attach operating room suction tubing to universal connector on handle assembly.
5.	Using a high-speed drill, create bone dust based on the procedure.

6.	Irrigate surgical site with saline to suspend the bone dust.
7.	Place the tip of the collection device into the saline/bone dust mixture and aspirate using suction system.
8.	Collect bone dust in the chamber and saline with blood products in the suction canister.
9.	Upon completely filling the collection chamber with bone dust, remove the tip and collect the bone dust with a flat instrument or spatula.
10.	Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc.
11.	If necessary, replace tip and collect additional bone dust.
12.	If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected.

[000165] In conjunction with FIG. 13 or FIG. 13A, and the foregoing disclosure, TABLE 2 below indicates detailed method steps for “Using the Self-Contained Bone Dust Collection Device with Syringe Suction.”

TABLE 2
USING THE SELF-CONTAINED DEVICE WITH SYRINGE SUCTION

Step No.	Description
1.	Open the single-pouch in a sterile fashion onto the operating room surgical field.
2.	Attach a 30 cc syringe to the luer lock of the device.

3.	Attach the right angle check valve assembly to the valve body.
4.	Using a high-speed drill, create bone dust based on the procedure.
5.	Suspend the bone dust using a small amount of saline irrigation.
6.	Place the tip of the collection device into the saline/bone dust mixture and aspirate by pulling back the syringe piston. Bone dust is collected in the chamber while saline and blood products are collected within the syringe.
7.	Recycle excess saline and blood collected within the syringe by pushing in the syringe piston allowing the excess fluid to be expelled through the side port back into the surgical wound.
8.	When the collection chamber is filled with bone dust, remove the tip and collect bone dust with a flat instrument or spatula.
9.	Pack the collected bone dust into the region of interest in the subject – interbody cage, bone defect, etc.
10.	If necessary, replace tip and collect additional bone dust.
11.	If necessary, repeat usage of the bone dust collection system until enough bone for the procedure has been collected.

[000166] In view of the foregoing, the embodiments of the present disclosure relate to a general method of collecting an anatomical specimen that includes the following steps.

[000167] With reference particularly to FIGS. 11, 12, 13 and 13A, the method includes generating an anatomical specimen, e.g., bone dust 180 (see FIG. 21) in particulate form at a surgical site of a subject (not shown).

[000168] The method includes irrigating the surgical site to suspend the particulate in a particulate fluid mixture (not shown). Upon irrigating the surgical site, the method includes disposing a tip of a collection device, e.g., the collection device 100 in FIG. 1, in the particulate fluid mixture (e.g., represented in FIG. 15B by arrows **F2A** and **F2B** internally within the collection device 100 in FIG. 1); aspirating the collection device, e.g., collection device 100, to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate, e.g., bone dust 180 in FIG. 17, in the collection device, e.g., collection device 100; and collecting the particulate, e.g., bone dust 180, accumulated in the collection device 100.

[000169] The method may further include packing the collected particulate, e.g., bone dust 180, into a region of interest in the subject (not shown).

[000170] The step of collecting the particulate accumulated in the collection device may be preceded by disassembling the collection device. The method may further include reassembling the collection device and repeating the foregoing steps of generating additional anatomical specimen in particulate form at a surgical site of the subject; irrigating the surgical site to suspend the particulate in a particulate fluid mixture; disposing the tip of the collection device in the particulate fluid mixture; aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and collecting the particulate accumulated in the collection device.

[000171] The method may then include again packing the additionally collected particulate, e.g., bone dust 180, into a region of interest in the subject.

[000172] As shown in FIGS. 11 and 12, the aspirating of the collection device 100 may include connecting the collection device 100 to a vacuum source, that

establishes suction through the handle assembly 500 in the proximal direction of arrow **S** in an operating room (not shown) wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture, shown by arrow B, to filter and separate the particulate, bone dust 180 from the particulate fluid mixture, shown by arrow B.

[000173] Alternatively, as shown in FIGS. 13 and 13A, the aspirating of the collection device 100 may include actuating a syringe, e.g., syringe 300, in fluid communication with the collection device 100 and in fluid communication with the particulate fluid mixture, shown by arrow B, wherein the actuating of the syringe effects filtering and separating the particulate, e.g., bone dust 180, from the particulate fluid mixture.

[000174] In conjunction with the foregoing disclosure and FIGS. 1-32, TABLE 3 indicates "Consideration for Using the Bone Dust Collection System or Device".

TABLE 3
CONSIDERATIONS FOR USING THE BONE DUST COLLECTION SYSTEM OR
DEVICE

Consideration No.	Description
1.	The device functions better with saline and bone dust mixture while minimizing the amount of blood.
2.	If there is too much blood in the field, the tip or filter may become clogged making it difficult to aspirate bone dust. The surgeon should irrigate the field, stop bleeding as much as possible, and try the procedure for bone dust collection at this point with a dry field.
3.	The tip may detach with excessive force while pushing into the wound to collect bone dust. Simply re-attach.

4.	Occasionally, the tip can become clogged with minimal saline. Irrigate further and simply put gentle pressure on the tip to dislodge stuck bone dust.
5.	The device is not a fusion device; it is intended to assist the surgeon in collecting bone dust.
6.	It is not expected that the device promotes better fusion rates.

[000175] The detailed description of exemplary embodiments herein makes reference to the accompanying drawings, which show the exemplary embodiments by way of illustration and their best mode. While these exemplary embodiments are described in sufficient detail to enable those skilled in the art to practice the disclosure, it should be understood that other embodiments may be realized and that logical and mechanical changes may be made without departing from the spirit and scope of the disclosure. Thus, the detailed description herein is presented for purposes of illustration only and not of limitation. For example, the steps recited in any of the method or process descriptions may be executed in any order and are not limited to the order presented. Moreover, any of the functions or steps may be outsourced to or performed by one or more third parties. Furthermore, any reference to singular includes plural embodiments, and any reference to more than one component may include a singular embodiment.

CLAIMS:

What is claimed is:

1. A bone dust collection device comprising:
a bone dust collection structure defining a longitudinal axis and having a proximal end and a distal end,
the bone dust collection structure having a transverse plate member connected at or in the vicinity of the proximal end to a cylindrical wall defining an aperture at the distal end for receiving and collecting bone dust, the aperture extending proximally and including a filtration member disposed therein, the filtration member configured and disposed wherein the filtration member causes at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member, the bone dust collection structure configured to enable removal of bone dust collected therein.
2. The bone dust collection device according to claim 1, wherein at least one aperture is defined in the transverse plate member that enables the fluid at least partially separated from the bone dust by the filtration member to pass therethrough.
3. The bone dust collection device according to claim 2, further comprising a flow interruption member configured and disposed with respect to the bone dust collection structure wherein flow of fluid through the at least one aperture of the bone dust collection structure occurs by suction pressure induced on the flow interruption member causing the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.
4. The bone dust collection device according to claim 3, wherein at least another aperture is defined in the transverse plate member wherein the flow interruption member includes a shaft member disposed through the at least another aperture wherein the change of position of the flow interruption member occurs via the suction pressure induced on the flow interruption member to enable flow through the at least one aperture defined in the transverse plate member.

5. The bone dust collection device according to claim 3, further comprising a syringe including a plunger in fluid communication with the bone dust collection structure wherein the suction pressure is caused by retraction of the plunger away from the bone dust collection structure to enable flow through the at least one aperture defined in the transverse plate member.

6. The bone dust collection device according to claim 5, wherein advancement of the plunger causes the flow interruption member to interrupt flow from the bone dust collection structure.

7. The bone dust collection device according to claim 6, further comprising a conduit in fluid communication with the bone dust collection structure, wherein advancement of the plunger causes the fluid received through the at least one aperture defined in the transverse plate member to discharge through the conduit away from the bone dust collection device.

8. The bone dust collection device according to claim 7, wherein the conduit is structured such that the conduit discharges the fluid in a direction generally perpendicular to the direction of fluid flow through the filtration member.

9. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein suction pressure induced on the another flow interruption device causes the another flow interruption device to be in a closed position and causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

10. The bone dust collection device according to claim 3, further comprising another flow interruption device configured and disposed with respect to the flow interruption device and with respect to the bone dust collection structure wherein the another flow

interruption device is a plug member to seal off flow therethrough during connection of the bone dust collection device to a continuous vacuum system and suction pressure induced on the flow interruption device causes the flow interruption member to change position to enable flow through the at least one aperture defined in the transverse plate member.

11. The bone dust collection device according to claim 1, further comprising:
a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure.
12. The bone dust collection device according to claim 11, wherein the bone dust removal structure includes a nozzle that defines the aperture of the bone dust removal structure, the nozzle defining a proximal end and a distal end, wherein the nozzle facilitates transport of the bone dust to the bone dust collection structure.
13. The bone dust collection device according to claim 12, wherein the nozzle is removably attached to the bone dust collection structure, wherein removal of the nozzle from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.
14. The bone dust collection device according to claim 3, further comprising a guide member configured and disposed with respect to the suction source and the bone dust collection structure for enabling a user to manually control the location of the bone dust removal structure during a surgical procedure.
15. The bone dust collection device according to claim 3, wherein the flow interruption member is an umbrella valve.

16. The bone dust collection device according to claim 9, wherein the another flow interruption member is a check valve.

17. A bone dust collection device comprising:

a bone dust collection structure defining a proximal end and a distal end, the bone dust collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting bone dust, the filtration member causing at least partial separation of fluid from the bone dust via the fluid passing proximally through the filtration member; and

a bone dust removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of bone dust from the distal end of the bone dust removal structure to the bone dust collection structure, the bone dust removal structure removably attached to the bone dust collection structure, wherein removal of the bone dust removal structure from the bone dust collection structure enables removal of bone dust collected within the bone dust collection structure.

18. An anatomical collection system comprising:

an anatomical specimen collection structure defining a proximal end and a distal end, the anatomical specimen collection structure including a filtration member at the proximal end and defining an aperture at the distal end for receiving and collecting an anatomical specimen, the filtration member causing at least partial separation of fluid from the anatomical specimen via the fluid passing proximally through the filtration member; and

an anatomical specimen removal structure defining an aperture having a proximal end and a distal end, the aperture configured and disposed for facilitating transport of the anatomical specimen from the distal end of the anatomical specimen removal structure to the anatomical specimen collection structure, the anatomical specimen removal structure removably attached to the anatomical specimen collection structure wherein detachment of the anatomical specimen removal structure from the

anatomical specimen collection structure enables removal of the anatomical specimen collected within the anatomical specimen collection structure.

19. The anatomical collection system according to claim 18, wherein the anatomical specimen is bone dust.

20. A method of collecting an anatomical specimen comprising:
generating an anatomical specimen in particulate form at a surgical site of a subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing a tip of a collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and
collecting the particulate accumulated in the collection device.

21. The method according to claim 20, further comprising:

packing the collected particulate into a region of interest in the subject.

22. The method according to claim 20, wherein the collecting the particulate accumulated in the collection device is preceded by disassembling the collection device, the method further comprising:

reassembling the collection device;

generating additional anatomical specimen in particulate form at a surgical site of the subject;

irrigating the surgical site to suspend the particulate in a particulate fluid mixture;

disposing the tip of the collection device in the particulate fluid mixture;

aspirating the collection device to filter and separate the particulate from the particulate fluid mixture therein accumulating the particulate in the collection device; and
collecting the particulate accumulated in the collection device.

23. The method according to claim 22, further comprising:
packing the additionally collected particulate into a region of interest in the subject.
24. The method according to claim 20, wherein the aspirating of the collection device includes connecting the collection device to a vacuum source wherein the vacuum source is in fluid communication with the fluid in the particulate fluid mixture to filter and separate the particulate from the particulate fluid mixture.
25. The method according to claim 24, wherein the connecting the collection device to a vacuum source includes connecting the collection device to a vacuum source in an operating room.
26. The method according to claim 20, wherein the aspirating of the collection device includes actuating a syringe in fluid communication with the collection device and in fluid communication with the particulate fluid mixture wherein the actuating of the syringe effects filtering and separating the particulate from the particulate fluid mixture.

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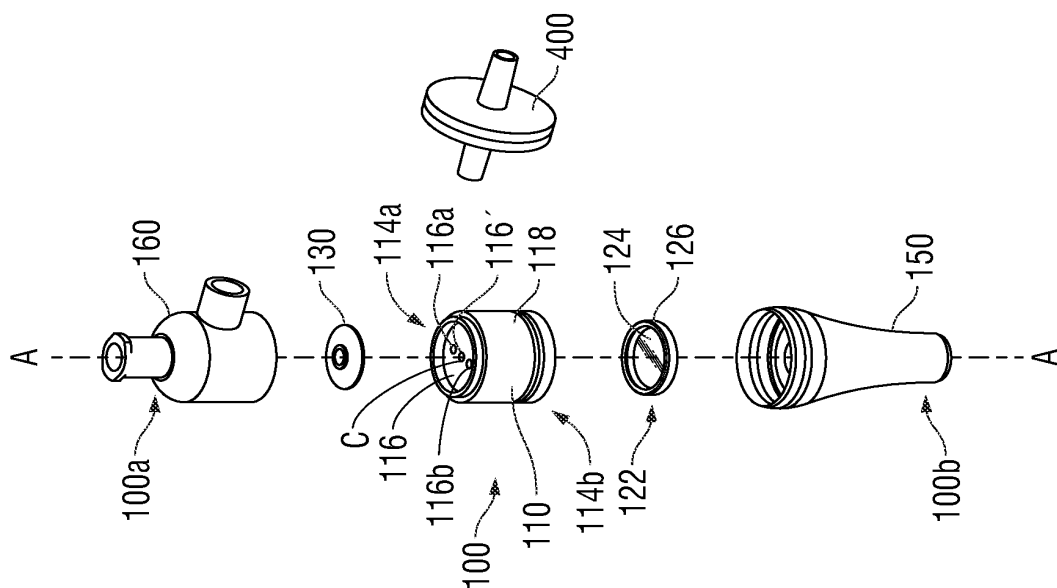


FIG. 2

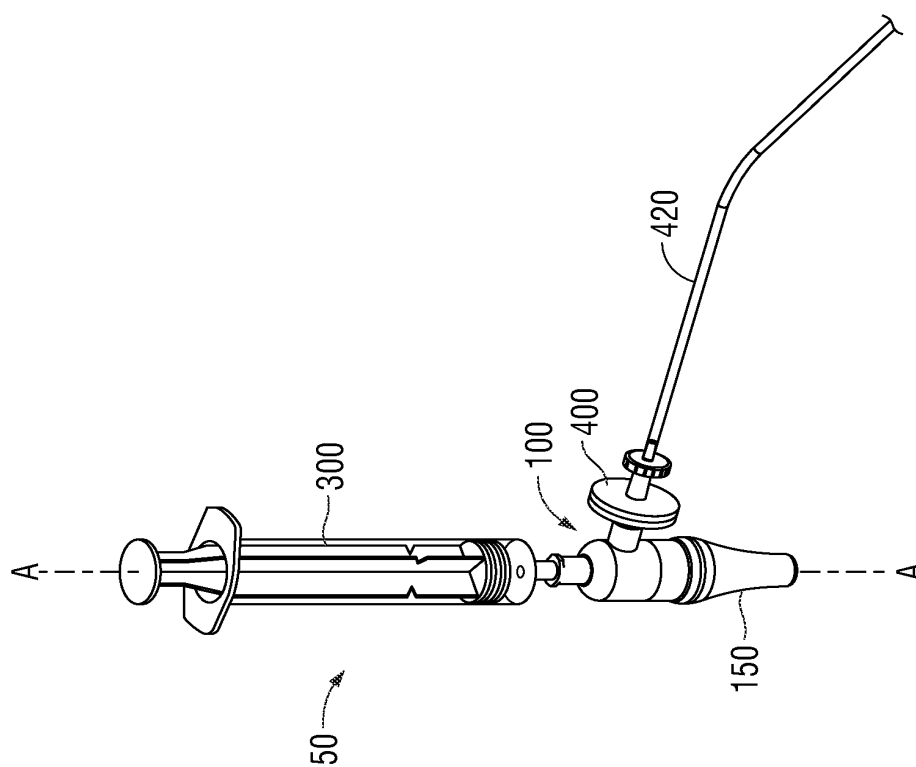


FIG. 1

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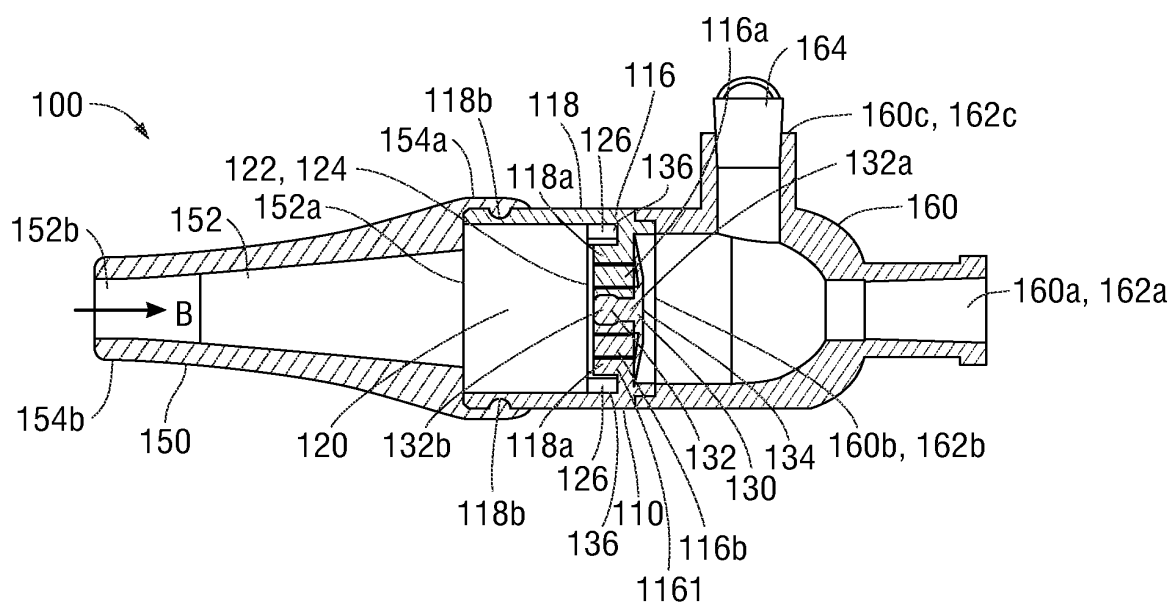


FIG. 3

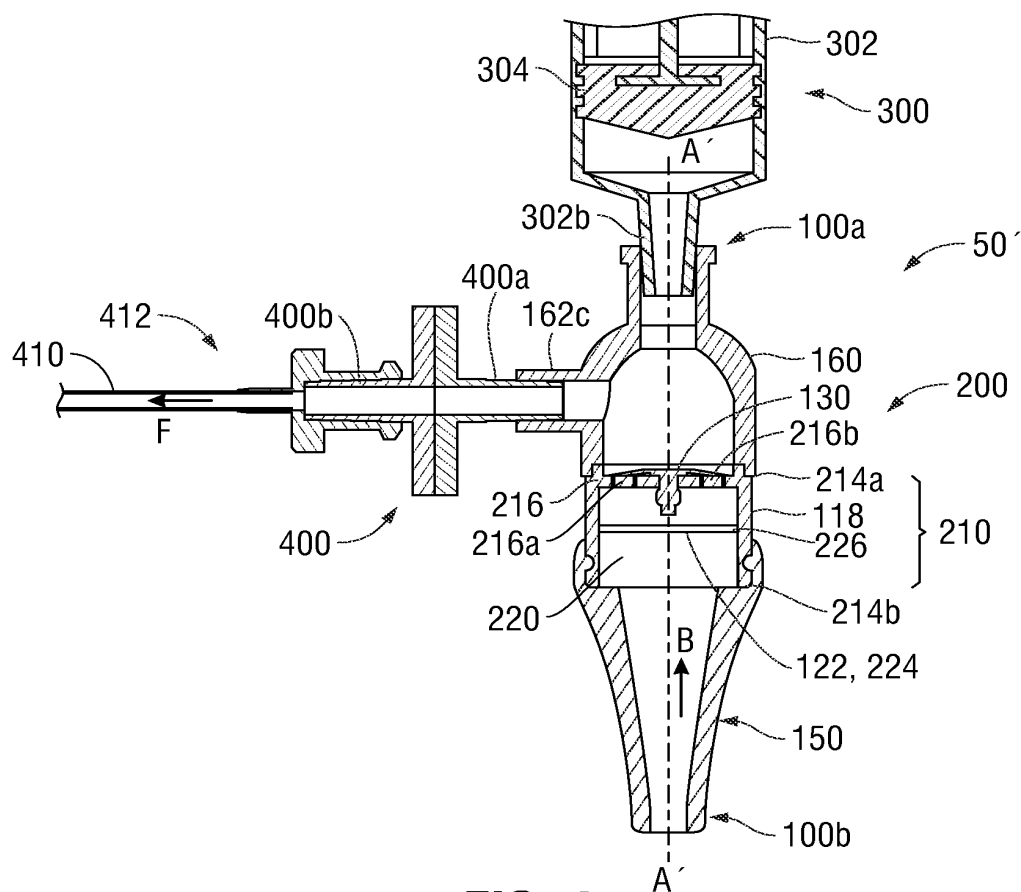


FIG. 4

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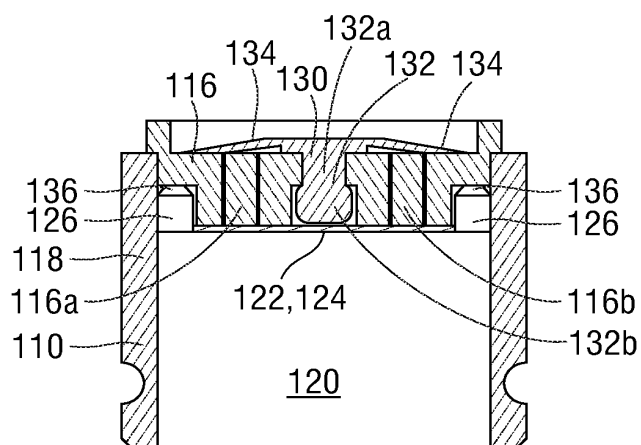


FIG. 5

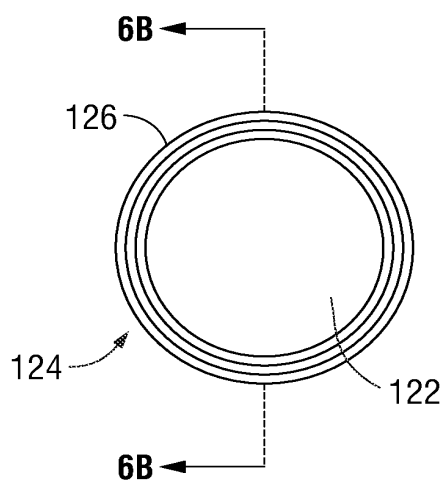


FIG. 6A

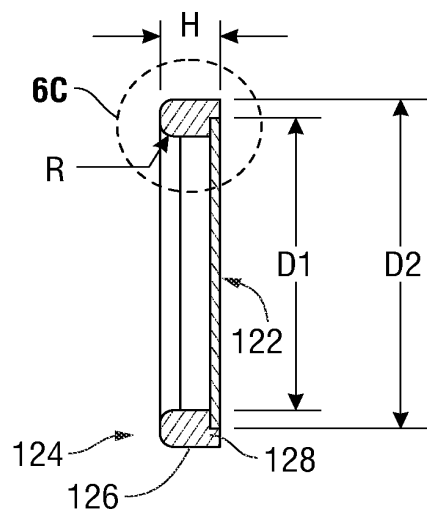


FIG. 6B

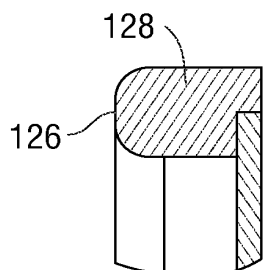


FIG. 6C

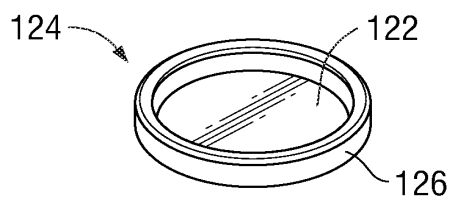


FIG. 6D

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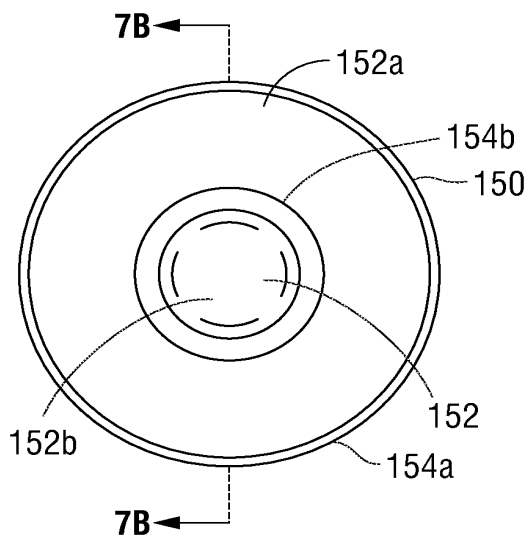


FIG. 7A

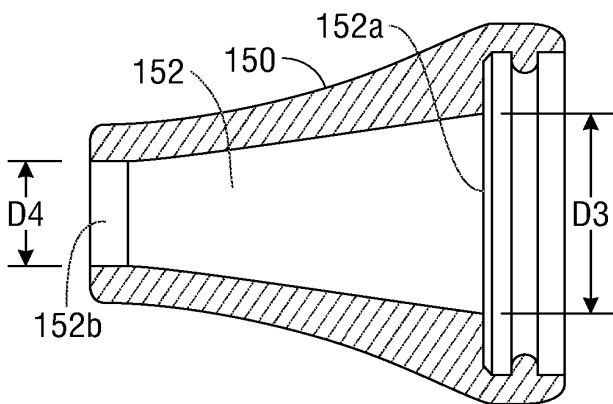


FIG. 7B

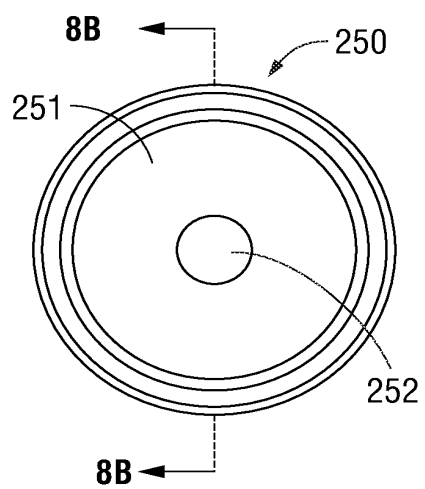


FIG. 8A

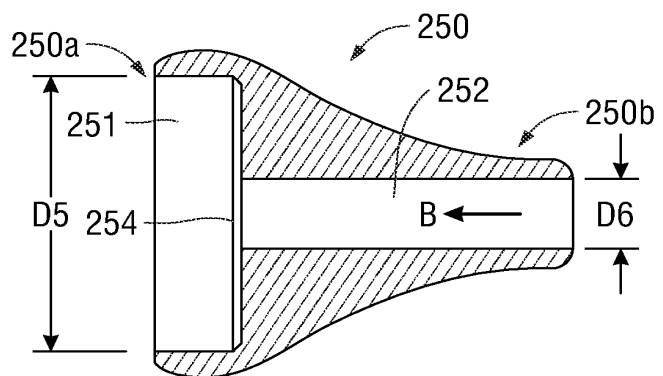


FIG. 8B

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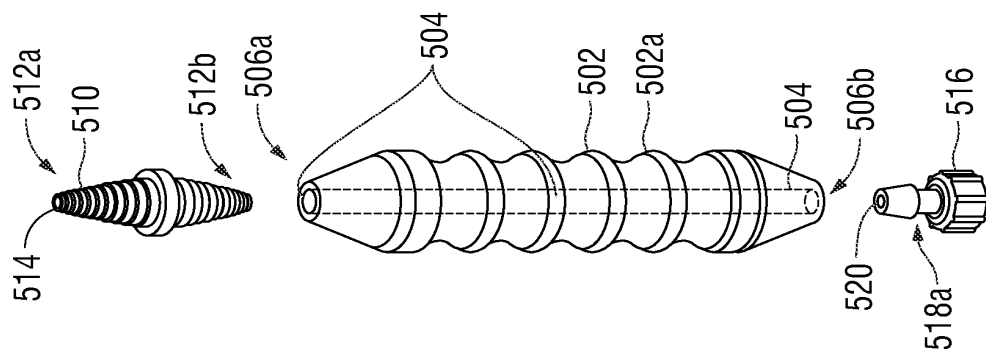


FIG. 10

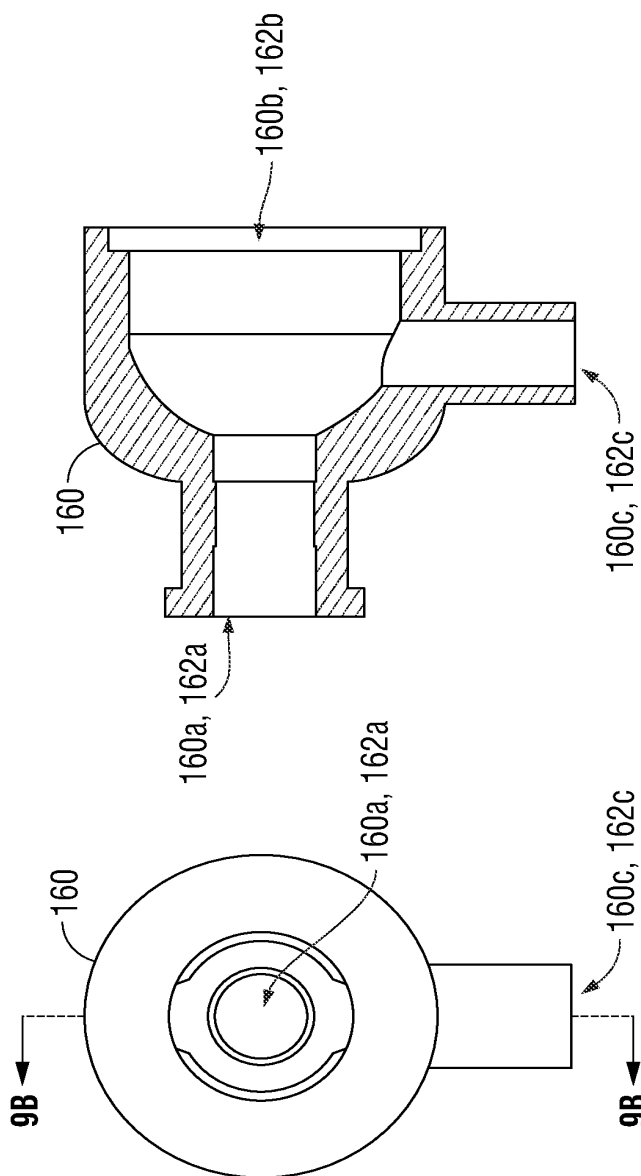


FIG. 9B

FIG. 9A

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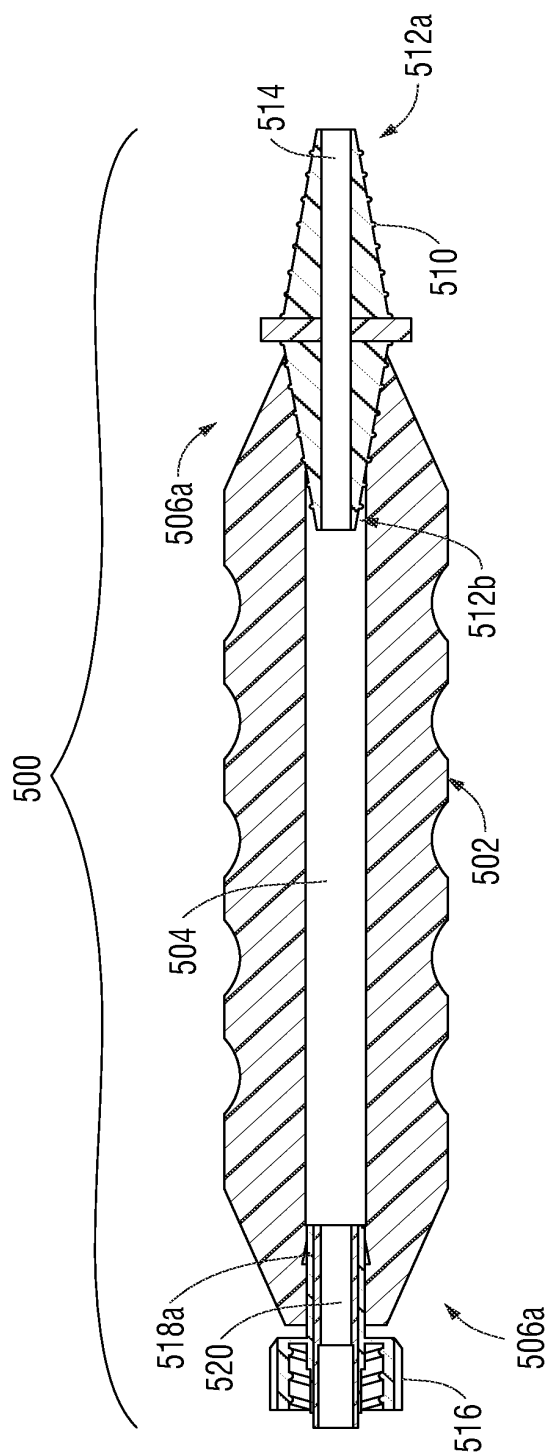


FIG. 10A

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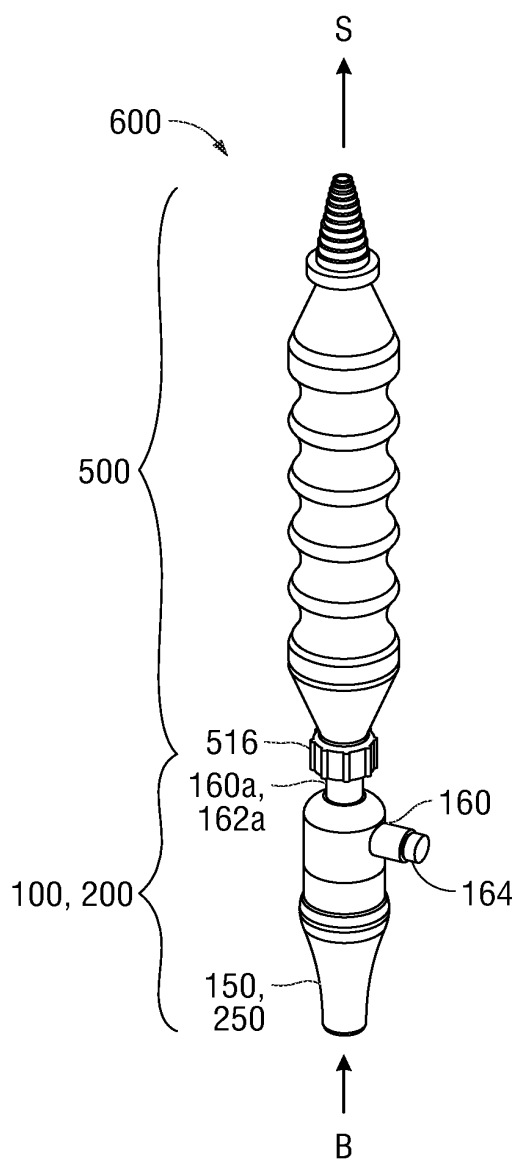


FIG. 11

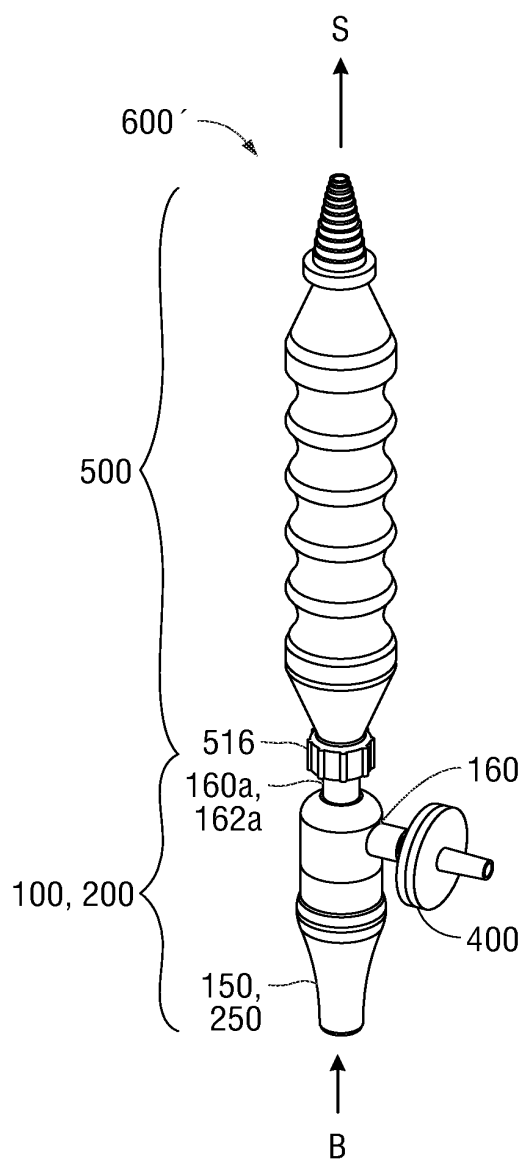


FIG. 12

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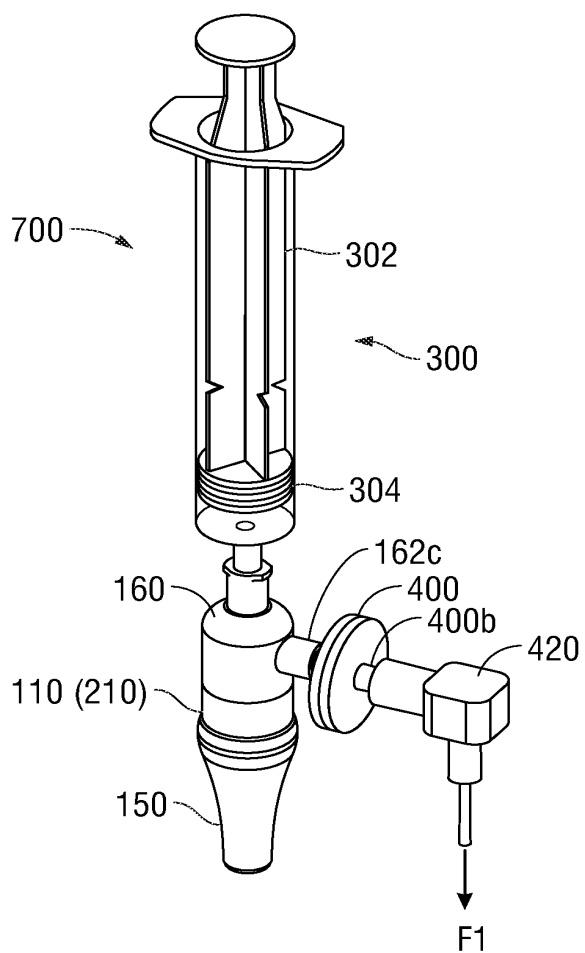


FIG. 13

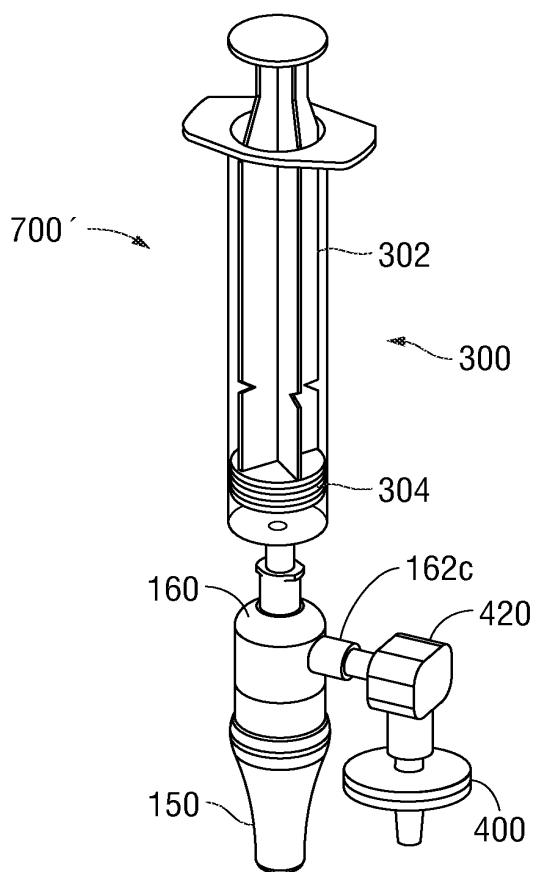


FIG. 13A

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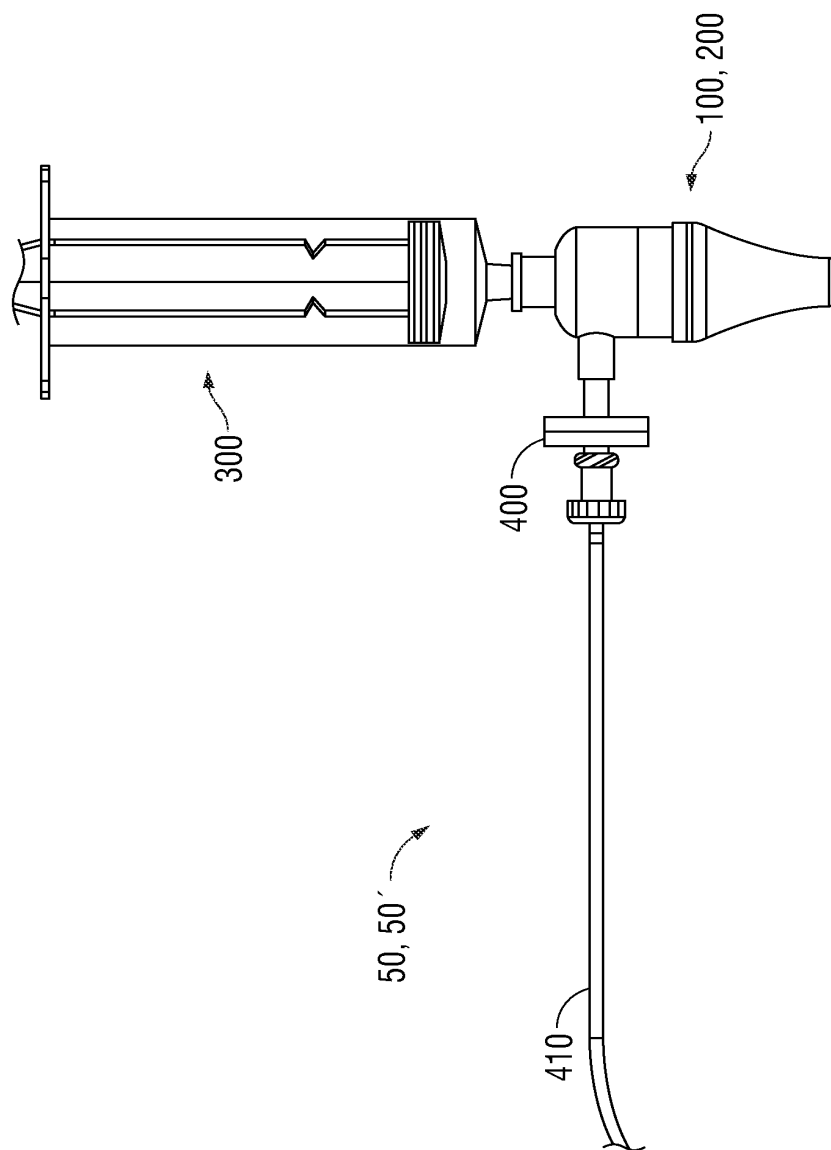


FIG. 14

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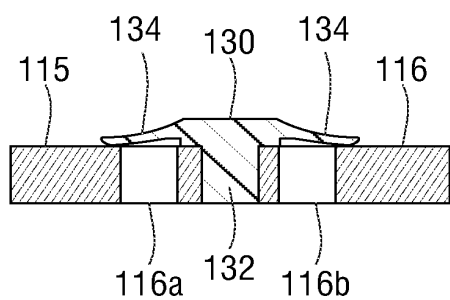


FIG. 15A

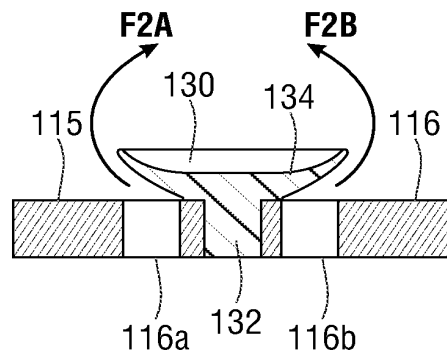


FIG. 15B

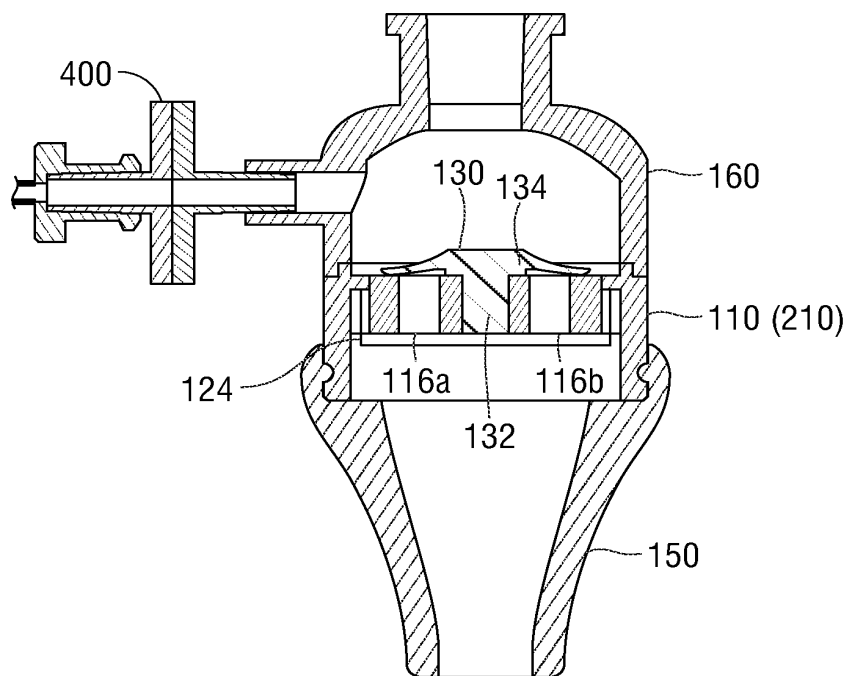


FIG. 16

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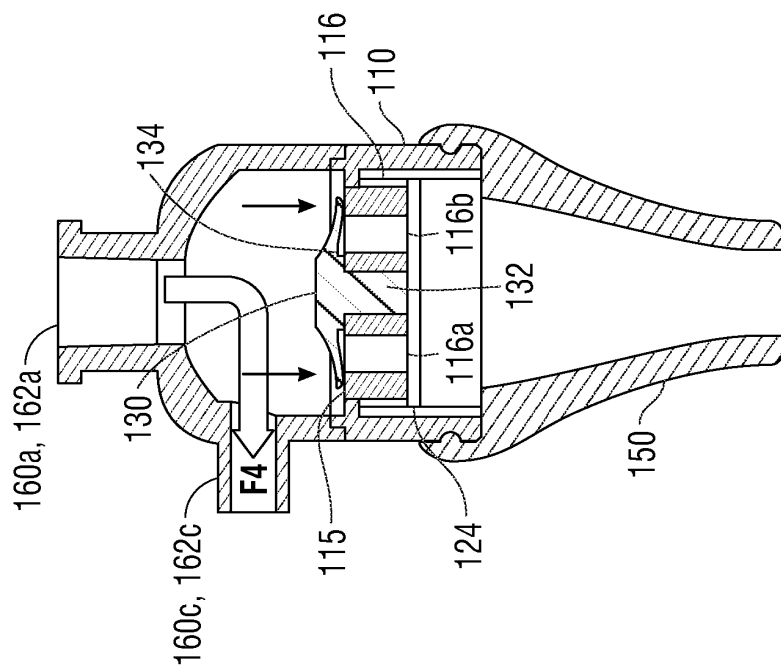


FIG. 17

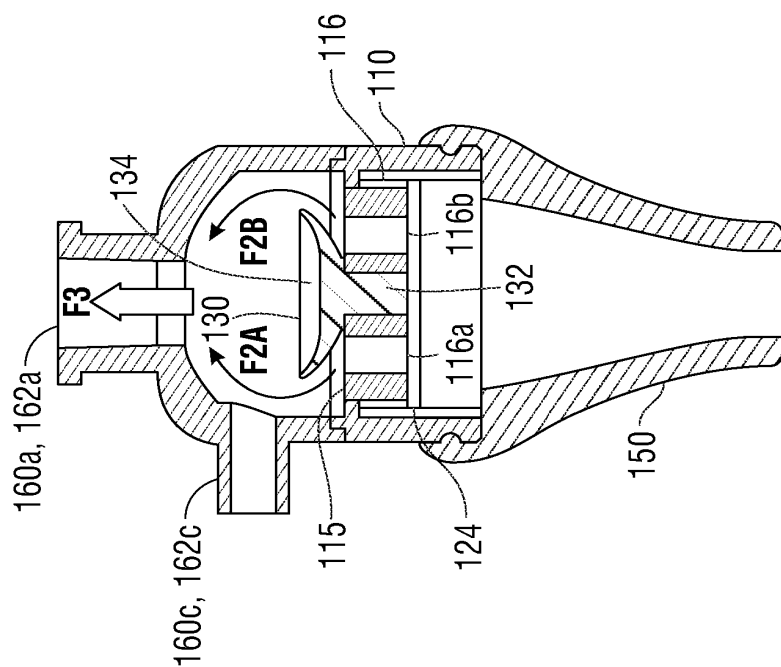


FIG. 18

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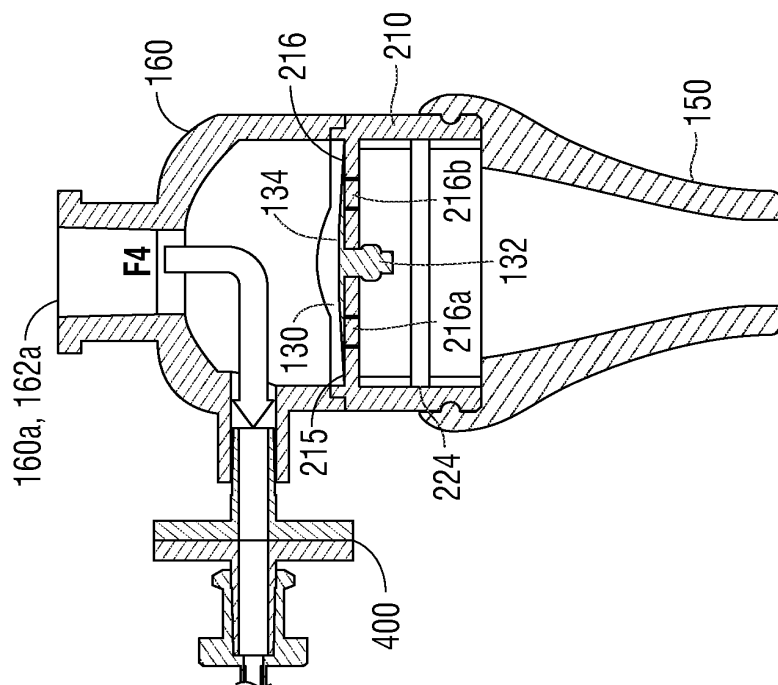


FIG. 20

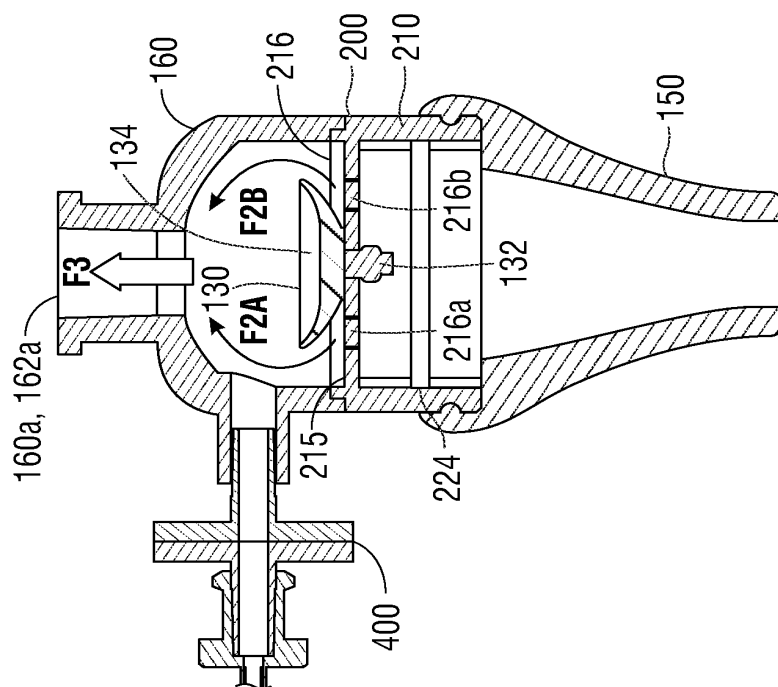


FIG. 19

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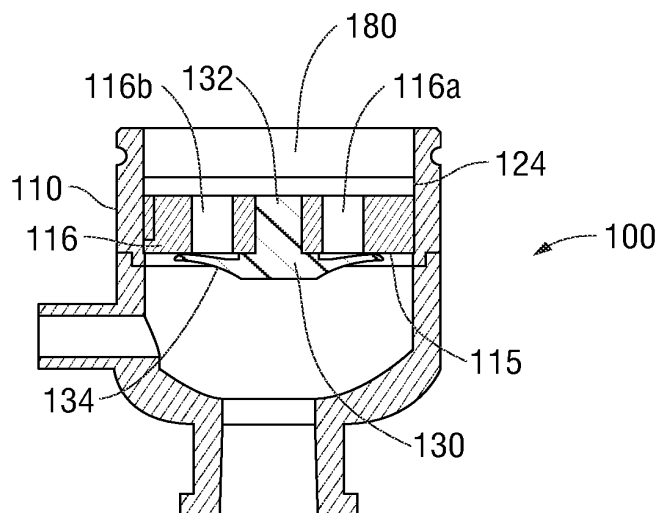


FIG. 21

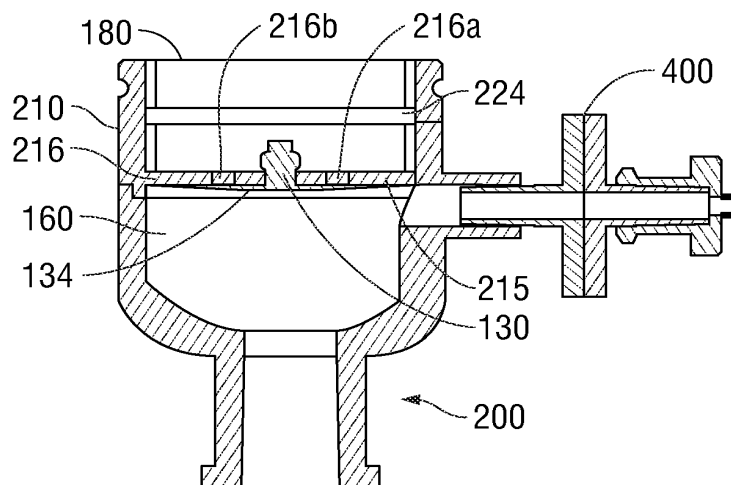


FIG. 22

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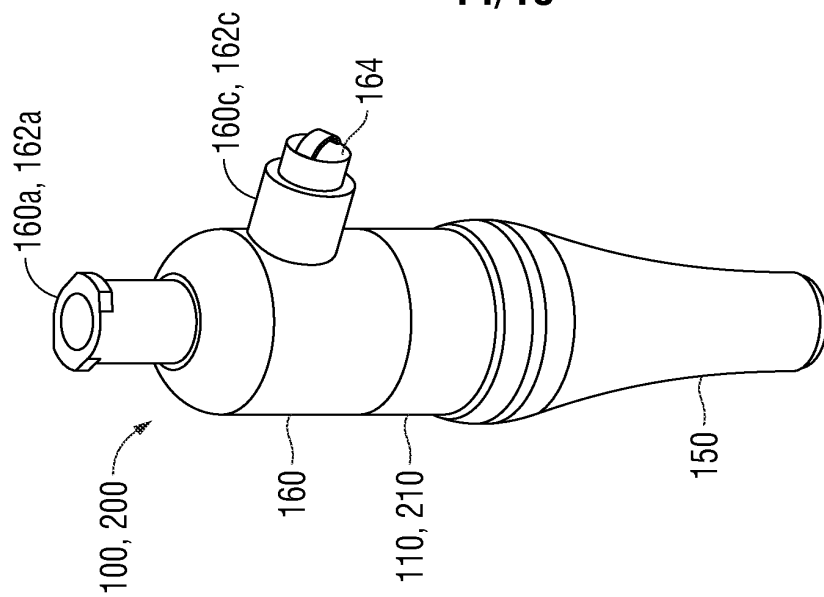


FIG. 24

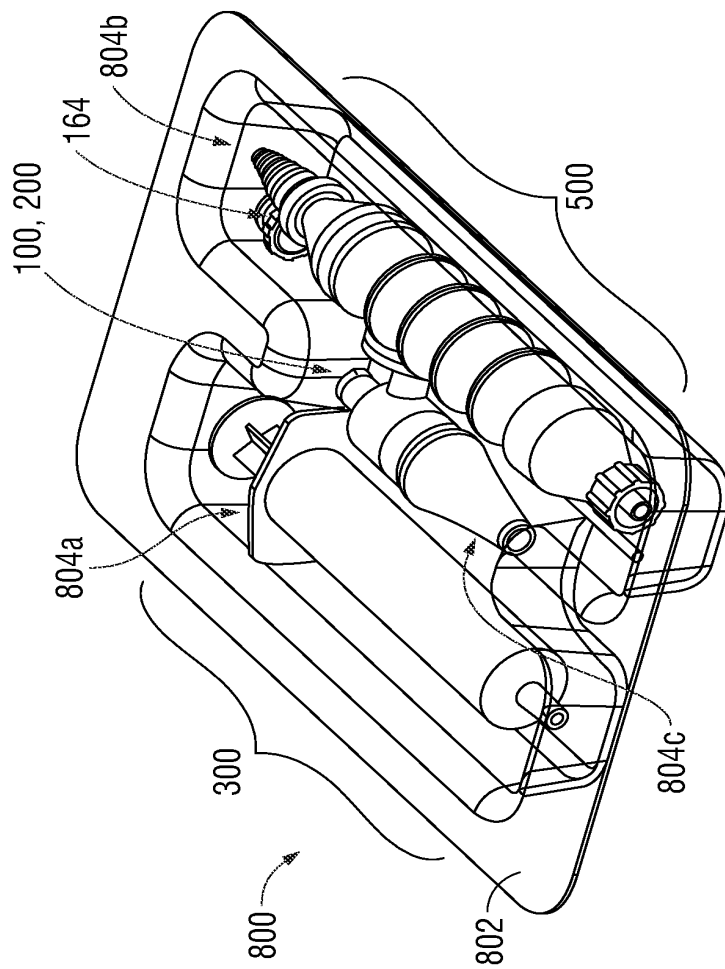


FIG. 23

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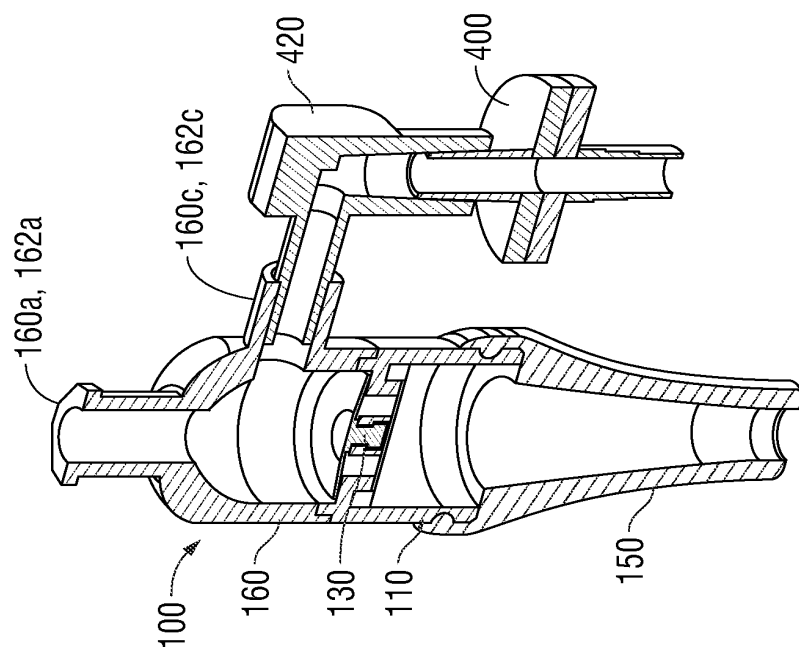


FIG. 26

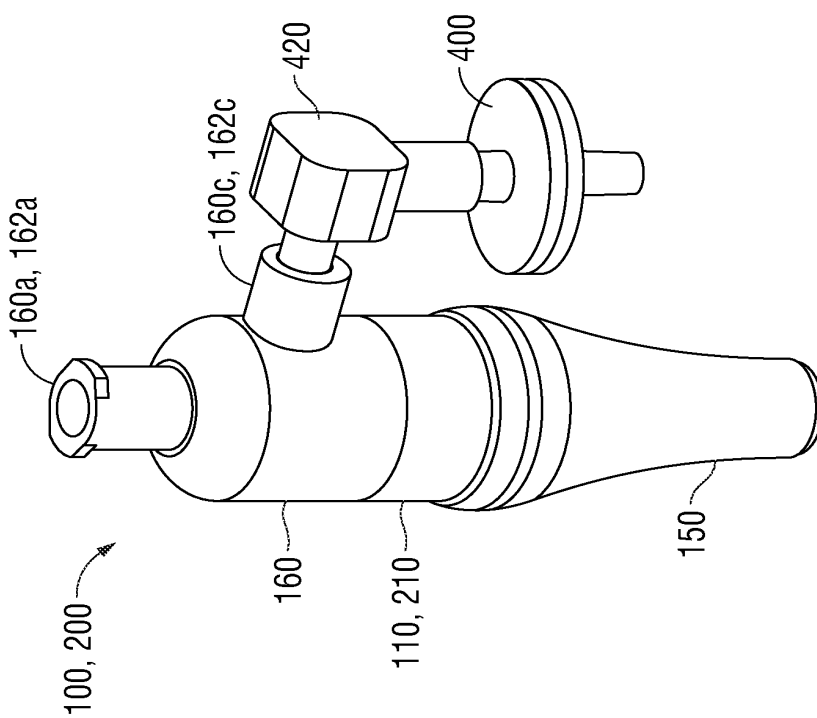


FIG. 25

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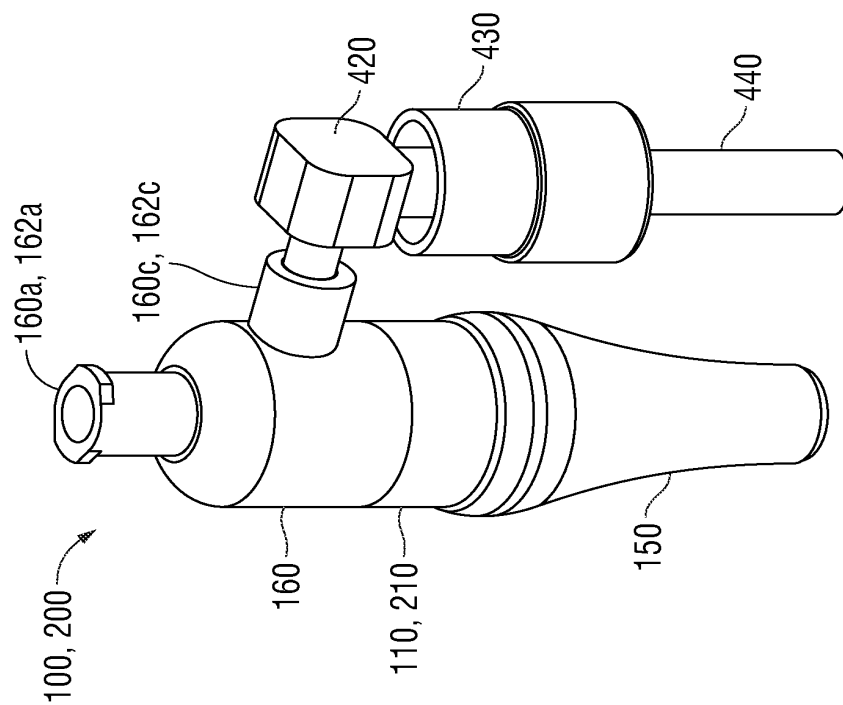


FIG. 27

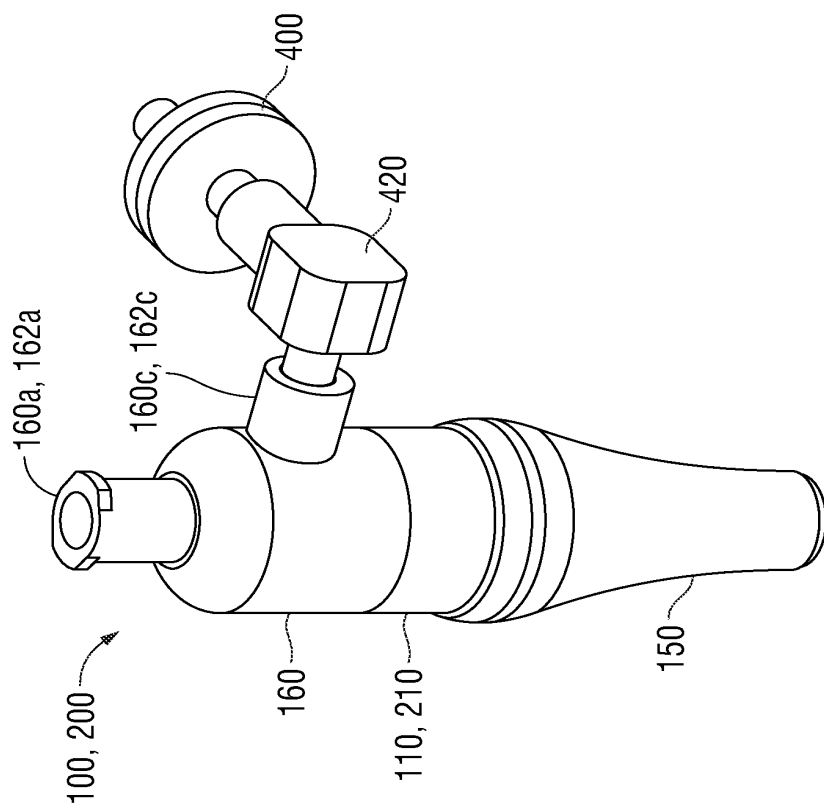


FIG. 28

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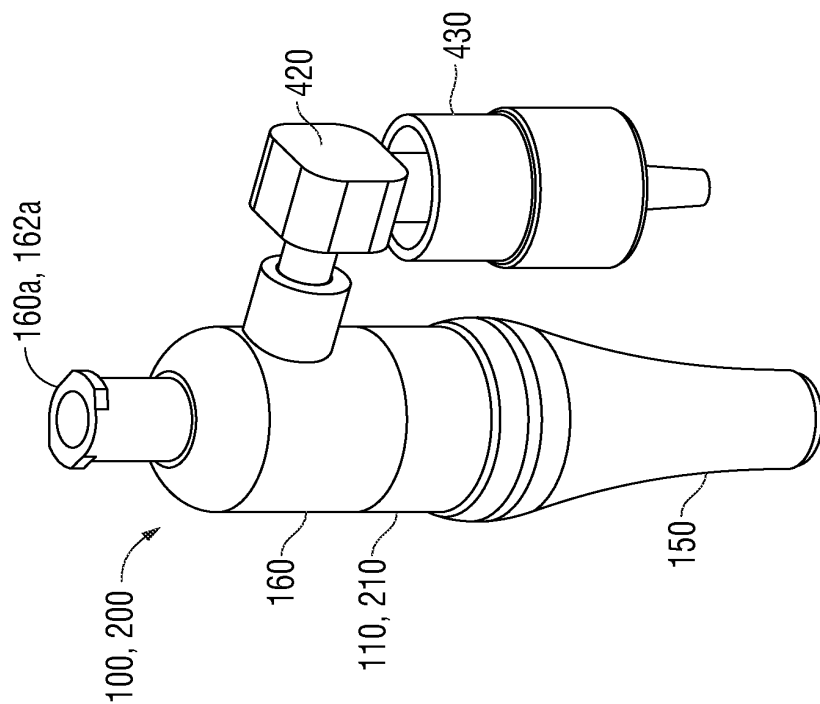


FIG. 30

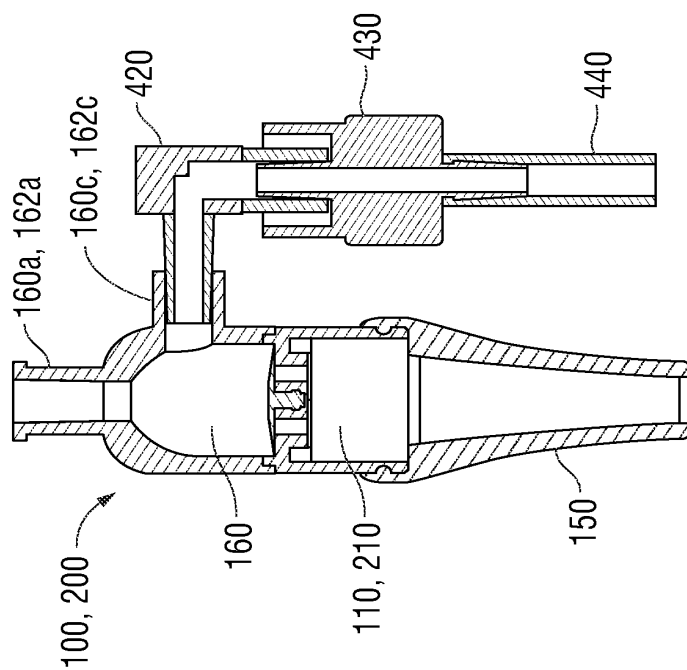


FIG. 29

18/18

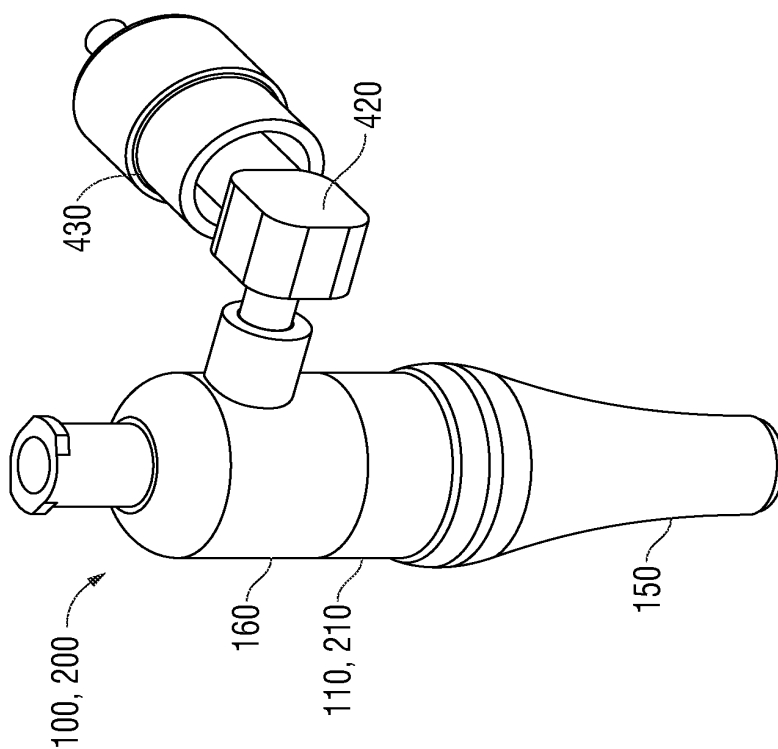


FIG. 32

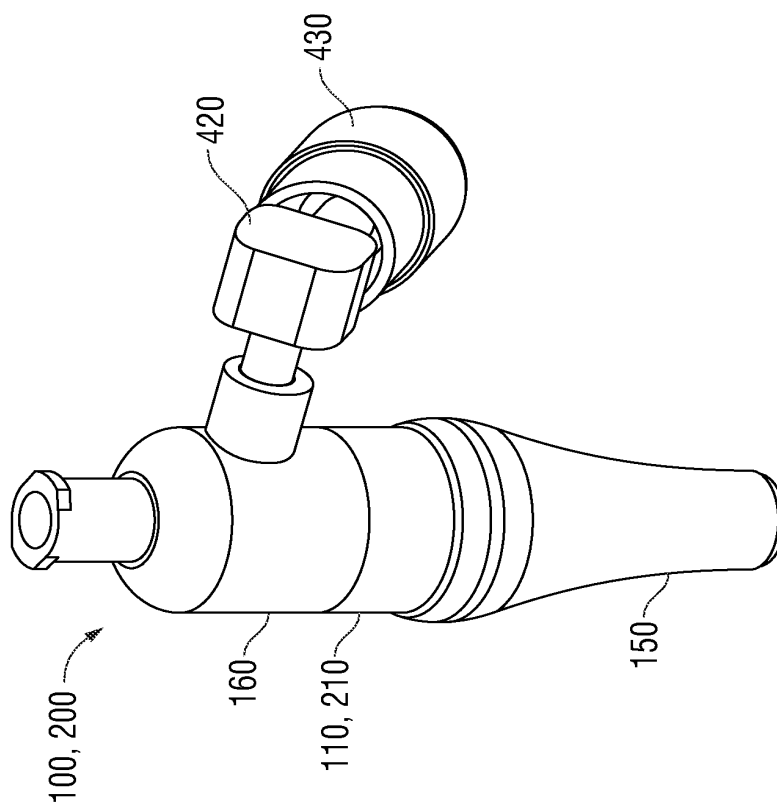


FIG. 31

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2015/042017

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/16 A61B10/02 A61M1/00
ADD. A61B17/32

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

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 202 427 033 U (YONGTUAN LI) 12 September 2012 (2012-09-12) figure 1 -----	1,2, 11-13, 17-19
X	CN 203 724 605 U (NANJING STOMATOLOGICAL HOSPITAL) 23 July 2014 (2014-07-23) figure 1 -----	1,2, 11-13, 17-19
X	JP H07 79997 A (KOMIYAMA YATARO; HATTORI MORIHIRO) 28 March 1995 (1995-03-28) figures 1,3 -----	1,2, 11-13, 17-19

☐

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

"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

2 November 2015

Date of mailing of the international search report

09/11/2015

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European Patent Office, P.B. 5818 Patentlaan 2
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/042017

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.: 20-26
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
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:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2015/042017

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
CN 202427033	U	12-09-2012	NONE	
CN 203724605	U	23-07-2014	NONE	
JP H0779997	A	28-03-1995	JP 2563237 B2 JP H0779997 A	11-12-1996 28-03-1995



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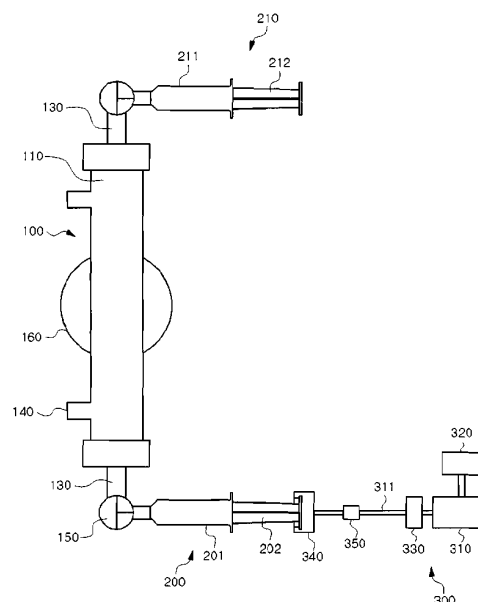
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85354 Freising (DE)

(54) Device and method for extracting concentrated plasma

(57) The present invention relates to a device and method for extracting concentrated plasma that includes a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma, a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma, a pressurizing means mounted in connection to the first receiving member so as to provide an injection rate and an injection pressure for the blood plasma, and a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member and open into a second space to hold air, where the second receiving member is allowed to open or close. This can pass the blood plasma through the membrane filter unit for a sufficient period of time using a predetermined pressure, gravity and vacuum, thereby maximizing the settlement of the platelets in the blood plasma flowing into the membrane filter unit, achieving filtration while the platelets settle down, minimizing the contact area between the platelets and a filter built in the membrane filter unit, and finally reducing the quantity of the platelets adsorbed onto the membrane to obtain platelet rich plasma containing a maximum quantity of platelets.

In addition, the concentrated plasma can be readily gelled simply by repeating the filtration or adding calcium.

FIG. 2



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Description

TECHNICAL FIELD

[0001] The present invention relates to a device and method for extracting concentrated plasma. More particularly, the present invention relates to a device and method for extracting concentrated plasma that is designed to extract concentrated plasma from the blood plasma removed of red blood cells.

BACKGROUND ART

[0002] In general, whole blood can be separated into blood corpuscles and blood plasma. The blood corpuscles fall into three general categories: red blood cells, white blood cells, and platelets. The blood plasma is mostly water, and contains clotting factors, electrolytes, and so forth.

[0003] To explain the blood plasma in further detail, the blood plasma consists of 60 to 85 % of water, 7 % of proteins, 1 % of fat, 0.1 % of sugar, and 0.9 % of other mineral ions. In this regard, the proteins in blood plasma can be classified into albumin and globulin, which are determined by using the difference in solubility in ammonium sulfate and individually consist of a combination of several proteins. The albumin constitutes about 55 % of the plasma protein and plays an important role in supplying proteins and maintaining the plasma colloid osmotic pressure. The globulin makes up about 38 % of the plasma protein and falls into one of the three categories: alpha globulin, beta globulin and gamma globulin. The alpha globulin contains lipoproteins and glycoproteins including fibrinogen and helps transport of vitamins, hormones, and so forth. The beta globulin performs a function as a carrier of prothrombin, plasma thromboplastin, iron, copper, or the like. The gamma globulin mostly contains immune antibodies.

[0004] The blood plasma, which plays a major role in the blood, can be injected into the human body to promote the transport of nutrient substances and thereby maximize its function such as inhibition of toxic substances.

[0005] Therefore, as illustrated in FIG. 1, the whole blood (Wb) is separated into red blood cells (RBCs), platelet rich plasma (PRP) and platelet poor plasma (PPP). Generally, the red blood cells are separated from the whole blood, and platelet rich plasma (PRP) and platelet poor plasma (PPP) are extracted. The platelet rich plasma (PRP) and the platelet poor plasma (PPP) are used in various treatment and cosmetic applications, including the treatment of wounds including sinus elevation surgery for dental implant, heart surgery, orthopedic surgery, dermatological treatment, and so forth.

[0006] In addition, the platelet poor plasma (PPP) is separated from the whole blood and contains proteins and a small quantity of platelets not isolated yet. Therefore, a reisolation process for the platelet poor plasma (PPP) is performed to re-extract the proteins and plate-

lets from the platelet poor plasma (PPP). For this purpose, the conventional method involves a repetition of centrifugal isolation and filtration on the platelet poor plasma (PPP).

[0007] However, even after the process of centrifugal isolation and filtration is done again on the platelet poor plasma (PPP) remaining after extraction of platelet rich plasma (PRP) from the blood plasma, the concentrated plasma re-extracted from the platelet poor plasma (PPP) has such a low content that it hardly contains a large quantity of proteins having a low molecular weight and not separated in the conventional process of centrifugal isolation and filtration. And, there is also a problem suggested in regards to the low efficiency of the conventional device and method that obtains concentrated plasma with low content.

Prior Documents

Patent Documents

[0008]

(Patent Document 1) KR20100116160 10

(Patent Document 2) KR20100041436 10

DISCLOSURE OF INVENTION

[0009] For solving the problems aforementioned, it is an object of the present invention to provide a device and method for extracting concentrated plasma that is designed to extract concentrated plasma with high concentration containing a maximum quantity of platelets while filtering the blood plasma out by passing the blood plasma removed of red blood cells through a filter by using a defined principle of pressure, gravity and vacuum.

[0010] To achieve the object of the present invention, there is provided a device for extracting concentrated plasma that includes: a membrane filter unit for isolating a component based on a predetermined particle diameter from blood plasma; and a first receiving member for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit and thereby to settle down platelets in the blood plasma.

[0011] The device further includes a pressurizing means mounted in connection to the first receiving member to provide the injection rate and the injection pressure of the blood plasma.

[0012] In this regard, the pressurizing means includes: a piston moving in connection to the membrane filter unit to inject the blood plasma in the first receiving member into the membrane filter unit; and a power source mounted to induce the movement of the piston.

[0013] The power source limits the moving distance of the piston to remain part of the blood plasma in the first receiving member for a predetermined period of time after the time that the blood plasma is completely injected

into the membrane filter unit.

[0014] The power source maintains the piston at a moved position for a predetermined period of time after the time that the movement of the piston is completed.

[0015] The power source moves the piston in a reverse direction at a predetermined speed in order to separate platelets, fibrinogens, proteins, and so forth filled in the filter after completion of the filtration.

[0016] The pressurizing means further includes: an adaptor for intermediating a coupling of a first plunger mounted in the first receiving member and the piston to inject the blood plasma in the first receiving member into the membrane filter unit; and a controller for controlling the operation of the power source to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston and the first plunger.

[0017] The pressurizing means further includes a direction-diverting switch for diverting the moving direction of the piston.

[0018] The membrane filter unit includes: a body having the first receiving membrane mounted thereon and including an inlet portion provided on either side portion of the membrane filter unit to exhaust air from the membrane filter unit when the blood plasma of the first receiving member flows in, and an outlet portion for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the membrane filter unit; a hollow filter being mounted in the body and having a second space for receiving a component having a particle diameter equal to or smaller than the predetermined particle diameter which is filtered when the blood plasma of the first receiving member flows in through the inlet portion; and a first space formed between the hollow filter and the body to open into the outlet portion to temporarily receive a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter and to exhaust the same through the outlet portion.

[0019] In addition, the membrane filter unit further includes a fixing member mounted on the body for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.

[0020] The device for extracting concentrated plasma according to the present invention further includes a second receiving member mounted on the membrane filter unit at a predetermined distance from the first receiving member to open into the second space 180 and receive air.

[0021] In this regard, the membrane filter unit further includes a valve mounted as an intermediate on a coupling portion between the inlet portion and the first and second receiving members. The valve is arranged to have the second space and the first receiving member open into each other at normal times. And, the valve is arranged to close the second space and the second re-

ceiving member when blood plasma is injected into the second space, and to open the second space into the second receiving member and inject air in the second receiving member into the second space when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space is to flow into the first receiving member.

[0022] On the other hand, according to the present invention, there is provided a method for extracting concentrated plasma that includes: a step S20 of injecting blood plasma into a membrane filter unit to settle down platelets in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter built in the membrane filter unit; and a step S40 of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit.

[0023] The method for extracting concentrated plasma according to the present invention further includes a step S10 of arranging the membrane filter unit in the upright position to reduce the contact area between the filter in the membrane filter unit and the platelets, before the filtering step S20.

[0024] The method for extracting concentrated plasma according to the present invention further includes a step S30 of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

[0025] The filtering step S20 includes injecting part of the blood plasma into the membrane filter unit. The first collecting step S40 includes collecting both a component having a particle diameter equal to or larger than the predetermined particle diameter which has passed through the filter and the remaining the blood plasma in one position.

[0026] The method for extracting concentrated plasma according to the present invention further includes a second collecting step S50 of injecting air into the membrane filter unit to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

[0027] In all the steps other than the collecting step, first and second spaces are formed by mounting a filter in a body of the membrane filter, where the second space holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter when the blood plasma flows in, and the second space momentarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter to exhaust the component through an outlet portion formed in the body of the membrane filter unit.

[0028] In addition, the filtering step S20 further includes a step S23 of injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure to settle down the platelets. Here, the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter mounted in the membrane filter unit during the filtration is equal to or lower than the permissible internal pressure of the filter.

[0029] The injecting step S23 includes using a pressurizing means to move a first plunger mounted on a first receiving member holding the blood plasma and push the blood plasma. As a power source of the pressurizing means moves a piston to move the first plunger mounted on the piston, thereby injecting the blood plasma into the second space at a predetermined injection rate and a predetermined pressure. When part of the blood plasma is injected into the second space, the remainder of the blood plasma remains in the first receiving member. After filtration, the first plunger is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

[0030] Further, air in a second receiving member mounted on the membrane filter unit is injected into the second space to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member holding the remaining blood plasma.

[0031] The first receiving member and the second receiving member are connected to the second space. Before the second collecting step S50, a valve is manipulated to have the second space open into the first receiving member and disconnect the second space from the second receiving member. In the second collecting step S50, the valve is manipulated to have the second space open into the first receiving member and the second receiving member.

[0032] In the filtering step S20, a valve 150 mounted on the opposite side of a first receiving member is closed to open into the membrane filter unit.

[0033] Therefore, in the filtering step S20, when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit to limit the injection height of the blood plasma to a predetermined height or below.

[0034] The method for extracting concentrated plasma according to the present invention further includes a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter, after the pressure-reducing step S30.

[0035] The collecting step S40 includes opening the valve to momentarily supply external air into the membrane filter unit and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.

[0036] In addition, the platelet rich plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit or adding calcium and then repeatedly filtering the blood plasma.

EFFECTS OF THE INVENTION

[0037] As described above, according to the present invention, the conventional process of separating platelet rich plasma and platelet poor plasma from the blood plasma can be omitted to simplify the process of extracting concentrated plasma which contains high concentration of platelets by passing the blood plasma removed of red blood cells through the membrane filter unit.

[0038] Further, the blood plasma can be passed through the membrane filter unit using a predetermined pressure and gravity for a sufficiently long period of time. This can allow the platelets in the blood plasma flowing into the membrane filter unit to settle down to the maximum, making it possible to perform the filtration while the platelets settle down, and minimize the contact area between the platelets and the filter built in the membrane filter unit. As a result, the quantity of the platelets adsorbed onto the membrane can be minimized, and the concentrated plasma can contain the maximum quantity of the platelets.

[0039] Furthermore, after the blood plasma is partly or completely injected into the membrane filter unit, the injection pressure is maintained for a predetermined period of time until the pressure in the membrane filter is sufficiently reduced. This can completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter and remaining in the membrane filter unit.

[0040] Moreover, the blood plasma is injected while the membrane filter unit is closed, so the injection height of the blood plasma can be limited to a predetermined height or below to prevent the contact between the blood plasma and the filter. This can minimize adsorption of the component in the blood plasma onto the filter.

[0041] In addition, the closed membrane filter unit is suddenly opened. This can flow away the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit momentarily, thereby readily releasing part of the components adsorbed onto the filter.

[0042] Further, the platelet rich plasma can be gelated by repeatedly filtering the blood plasma collected in the membrane filter unit or adding calcium to the blood plasma and then repeatedly filtering it.

BRIEF DESCRIPTION OF DRAWINGS

[0043] The accompanying drawings, which are incorporated the specification, illustrate a preferred embodiment of the present invention and serve to explain the principles of the invention. It should be apparent that the accompanying drawings are not construed to limit the

scope of the present invention. In the drawings:

FIG. 1 is a side diagram showing the whole blood under centrifugal separation.

FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention.

FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2.

FIGS. 4a and 4b are operational diagrams of FIG. 2.

FIG. 4c is a constructional diagram showing that a second receiving member is excluded in the membrane filter unit of FIG. 2.

FIG. 5 is a flow chart showing a first extraction method for concentrated plasma using the extracting device of FIG. 2.

FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2.

BEST MODES FOR CARRYING OUT THE INVENTION

[0044] Hereinafter, a detailed description will be given as to the preferred embodiments of the present invention with reference to the accompanying drawings so as for those skilled in the art to readily carry out the present invention. But, in the detailed description of the operational principles regarding the preferred embodiments of the present invention, the specific description as to the known functions or constructions is to be excluded when it is considered to unnecessarily depart from the conception of the present invention.

<Construction>

[0045] FIG. 2 is a schematic constructional diagram showing a device for extracting concentrated plasma according to a preferred embodiment of the present invention. FIG. 3 is a cross-sectional diagram showing the inside of the membrane filter unit shown in FIG. 2. FIGS. 4a and 4b are operational diagrams of FIG. 2.

[0046] The device for extracting concentrated plasma according to the present invention includes, as shown in FIG. 2, a membrane filter unit 100, a first receiving member 200, a second receiving member 210, and a pressurizing means 300.

[0047] The membrane filter unit 100 is a member for filtering blood plasma in order to exhaust a component having a particle diameter equal to or smaller than a predetermined particle diameter which is contained in the blood plasma. In this regard, the blood plasma used to extract platelet rich plasma in the present invention is preferably a blood plasma obtained by removing the whole blood of red blood cells through centrifugal separation, or it may be a platelet poor plasma generally available.

[0048] The membrane filter unit 100 includes a body

110, a filter 120 mounted in the body 110 and designed to have a component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through, an inlet portion 130 formed on either side portion of the body 110 and individually having the first and second receiving members 200 and 210, an outlet portion 140 mounted in the body 110 to exhaust the component of a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120, a three-way valve 150 mounted to open/close the inlet portion 130, and a fixing member 160 for maintaining the body 110 in the upright position.

[0049] In this regard, the membrane filter unit 100 is to separate platelets, proteins, albumins, etc. from water, uric acid, potassium, phosphates, etc. as contained in the blood plasma. For separation, the cross-sectional area of the filter 120 is preferably about 0.04 m² to 0.08 m², more preferably about 0.06 m².

[0050] The membrane filter unit 100 may be an example of membrane filter unit, which is preferably used for blood osmosis. Of course, the membrane filter unit 100 may be a general filter capable of filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter, such as platelets, proteins, albumins, etc. of the blood plasma, in addition to the membrane filter unit.

[0051] On the other hand, the filter 120 is built in the body 110, and the inlet portion 130 and the outlet portion 140 are formed on either side portion of the body 110. The body 110 preferably has a cylindrical shape, or it may have a polygonal pillar shape such as a rectangular pillar shape.

[0052] Between the inner wall of the body 100 and the filter 120 is formed a defined first space 170, which temporarily receives a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120. In other words, the first space 170 is an independent space disconnected from the inlet portion 130.

[0053] The filter 120 is a member through which a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed. The filter 120 has a hollow cylindrical shape or a hollow polygonal pillar shape that forms a second space 180 into which the blood plasma flows. In this regard, the second space 180 directly opens into the inlet portion 130 to have the blood plasma enter from the inlet portion 130. Accordingly, when the blood plasma flows into the second space 180, a component having a particle diameter equal to or smaller than the predetermined particle diameter in the blood plasma is passed through the filter 120 and flows into the first space 170, and a component having a particle diameter equal to or larger than the predetermined particle diameter in the blood plasma remains in the second space 180.

[0054] In this regard, there can be a modification of the embodiment in such a manner that the filter 120 has a panel shape and divides the inside of the body 110 into

the first and second spaces 170 and 180, where the first space 170 opens into the outlet portion 140 and the second space 180 opens into the inlet portion 130.

[0055] In addition, the inlet portion 130 is formed on either side portion of the body 110. The first receiving member 200 receiving the blood plasma is mounted on the inlet portion 130 formed on the one side of the body 110, and the second receiving member 210 receiving air is mounted on the inlet portion 130 formed on the other side of the body 110. The inlet portion 130 is formed in direct connection to the second space 180 of the filter 120. This is not only to have the blood plasma of the first receiving member 200 flow directly into the second space 180 but also to have a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 flow into the first receiving member 200 by the pressure applied by the second receiving member 210. Other details in regards to the inlet portion 130 will be described later in association with the three-way valve 150.

[0056] In addition, the outlet portion 140 is formed on the one side of the body 100 or on either side of the body 100 to open into the first space 170. This is to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter and flowing into the first space 170 through the filter 120.

[0057] The three-way valve 150 is mounted on either coupling portion of the inlet portion 130 and the first and second receiving members 200 and 210. The three-way valve 150 is operated to disconnect the first receiving member 200 and the second space 180 from the second receiving member 210 while the blood plasma of the first receiving member 200 is flowing into the second space 180 of the filter 100. Further, the three-way valve 150 is operated to have the second receiving member 210 open into the second space 180 and the first receiving member 200 so that, after the filtration of the blood plasma is completed, the air in the second receiving member 210 enters the second space 180 to flow a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200.

[0058] The fixing member 160 is a member for maintaining the membrane filter unit 100 in the upright position, and it may be any general member designed so that the body 110 can be put in it, suspended from it, inserted into it or picked up from it. The fixing member 160 is excluded when the membrane filter unit 100 is used in a position other than the upright position. For this purpose, the membrane filter unit 100 is formed to have a wider bottom portion or to have a varied shape designed not to let off the blood plasma from the inlet portion 130 when the membrane filter unit having a cylindrical shape is laid on the side. In this case, there is no need of using the membrane filter unit in the upright position, if the platelets in the blood plasma settle down and have a minimum contact area with the filter 120.

[0059] In this regard, the purpose of using the fixing

member 160 to fix the membrane filter unit 100 in the upright position is having the blood plasma flow in from the bottom portion of the body 110 and carrying out the filtration while the platelets in the blood plasma settle down under the effect of gravity. The settlement of the platelets minimizes the contact area between the platelets and the filter 120 to reduce the adsorption of the platelets onto the filter 120 to the minimum. This can minimize a loss of the platelets caused by the adsorption onto the filter 120 and render a maximum amount of platelets contained in the platelet rich plasma that is going to be extracted later.

[0060] The first receiving member 200 is a member for receiving the blood plasma, injecting it into the membrane filter unit 100 and collecting the filtered blood plasma, that is, platelet rich plasma. The first receiving member 200 includes a first receiving portion 201 for receiving the blood plasma or the platelet rich plasma obtained after the filtration and a first plunger 202 mounted to push the blood plasma in the first receiving portion 201 into the second space 180 of the membrane filter unit 100. The first receiving member 200 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing the blood plasma or receiving the concentrated plasma after the filtration.

[0061] On the other hand, the second receiving member 210 is a member for receiving air and injecting it into the second space 180 of the membrane 100 after the filtration to push a component having a predetermined particle diameter or a larger particle diameter remaining in the second space 180 into the first receiving member 200. The second receiving member 210 includes a second receiving portion 211 for receiving air and a second plunger 212 mounted to inject the air in the second receiving portion 211 into the second space 180 of the membrane filter unit 100. The second receiving member 210 is preferably, for example, a syringe without a needle, and it may be constructed to include at least two separate members for receiving or pushing air. In this regard, the mounting positions of the first and second receiving members 200 and 210 are the bottom portion and the top portion, respectively, and exchangeable with each other.

[0062] The pressurizing means 300 is a means for injecting the blood plasma in the first receiving member 200 into the second space 180 under a predetermined pressure, and includes a power source 310 having a piston 311 mounted to push or pull the first plunger 202. In addition to the power source 310, the pressurizing means 300 may further include a controller 320 mounted to control the operation of the power source 310, a decelerator 330 mounted on the power source 310, an adaptor 340 mounted to intermediate a coupling of the first plunger 202 and the piston 311, and a direction-diverting switch 350 mounted to divert the moving direction of the piston 311. In this regard, the piston 311 without the first plunger 202 may move by directly sliding inside the first receiving

member 200.

[0063] First of all, the power source 310 is a device that enables the piston 311 coupled to the first plunger 202 of the first receiving member 200 to make a reciprocating movement in order to push or pull the first plunger 202. The power source 310 is preferably, for example, a motor. Otherwise, the power source 310 may also be a device with a separate piston 311 that enables the piston 311 to make a reciprocating movement.

[0064] In this regard, the pressure applied to inject the blood plasma into the membrane filter unit 100, that is, the pressure provided by the power source 310 may be equal to the permissible internal pressure of the filter 120 or below. For example, when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is preferably in the range of about 300 to 450 mmHg.

[0065] In addition, the power source 310 provides an injection rate that allows the platelets in the blood plasma to settle down under the effect of gravity while the blood plasma is injected into the second space 180.

[0066] The controller 320 controls all the functions of the power source 310, including determination on whether to operate the power source 310 or not, the torque, that is, the magnitude of the pressure to inject the blood pressure into the second space 180, the running time, the moving distance of the piston 311, the moving direction of the piston 311, the stand-by time after movement of the piston 311, the injection pressure and the injection rate of the blood plasma, and so forth.

[0067] In one embodiment for extracting concentrated plasma from blood plasma, 5 portions of platelet rich plasma can be obtained by combining 3 portions of a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 and 2 portions of a blood plasma remaining in the first receiving member 200. For this purpose, the first plunger 202 in the first receiving member 200 moves only to the scale of 2 in the first receiving member 200 and then stops until a component having a particle diameter equal to or smaller than the predetermined particle diameter is completely exhausted through the outlet portion 140. The movement of the piston 311 in association with the movement of the first plunger 202 is under the control by the controller 320. It is of course possible to obtain 5 portions of the platelet rich plasma by injecting all the blood plasma of the receiving member 200 into the membrane filter unit 100 and filtering out a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180.

[0068] In another embodiment for extracting concentrated plasma from blood plasma, 6 or 7 portions of platelet rich plasma can be obtained by combining 3 portions of the component having particle diameter equal to or larger than a predetermined particle diameter and remaining in the second space 180 and 3 or 4 portions of blood plasma remaining in the first receiving member

200. For this, the first plunger 202 moves only to the scale of 3 or 4 in the first receiving member 200 and then stops. The movement of the piston 311 is also under the control by the controller 320.

[0069] In other words, the controller 320 controls the movement of the piston 311 so that the quantity of the blood plasma remaining in the first receiving member 200 is regulated according to a desired amount of the component having a particle diameter equal to or larger than the predetermined particle diameter in the membrane filter unit 100.

[0070] Contrarily, the controller 320 can simply set the torque range of the power source 310 and control the power source 310 to operate within the range of the predetermined torque. In this case, each of the other functions of the power source 310 aforementioned can be activated independently or at least two of the other functions can be activated simultaneously, by way of separate switches or control buttons.

[0071] The decelerator 330 enhances the torque of the power source 310 and enables the stable occurrence of the torque.

[0072] The adaptor 340 is an intermediate for a stable coupling of the piston 311 and the first plunger 202. The one side of the adaptor 340 is firmly coupled to the first plunger 202, and the other side of the adaptor 340 is fixed to the piston 311.

[0073] The direction-diverting switch 350 is mounted to divert the moving direction of the piston 311 for injecting the blood plasma into the second space 180 or collecting a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 after the filtration. The direction-diverting switch 350 may be excluded, in which case the power source 310 can directly divert the moving direction of the piston 311. For example, when the power source 310 is a motor, it can divert the moving direction of the piston 311 by changing its rotational direction.

<Examples>

[0074] FIG. 4c is a constructional diagram showing the membrane filter unit of FIG. 2 without the second receiving member.

[0075] FIG. 4c is almost the same in construction as FIG. 2, excepting that the second receiving member 210 is excluded. Such a construction of FIG. 4c is to carry out a second method mentioned later, and its detailed description will be given in association with the description of the second method.

<First Method>

[0076] FIG. 5 is a flow chart showing a method for extracting concentrated plasma using the extracting device of FIG. 2.

[0077] Firstly, the membrane filter unit 100 is fixed in

the upright position, in step S10. The arrangement is to make the platelets in the blood plasma settle down under the effect of gravity and then to filter the blood plasma. This can minimize the contact area between the platelets and the filter 120 and thereby reduce a loss of the platelets caused by the adsorption onto the filter 120.

[0078] Subsequently, the blood plasma is injected into the membrane filter unit 100 to undergo filtration, while allowing the platelets to settle down, in step S20. For this purpose, there is included a step S21 of receiving the blood plasma in the first receiving member 200 and then mounting the first receiving member 200 on the membrane filter unit 100. In this regard, the first receiving member 200 is mounted on the inlet portion 130 formed on the one side of the body 110 of the membrane filter unit 100, so it opens to the second space in the body 110. In this construction, the first receiving member 200 and the inlet portion 130 are coupled together via the three-way valve 150, which is manipulated to open or close the first receiving member 200 and the second space 180. For injecting the blood plasma into the second space 180, the three-way valve 150 can be manipulated to open the first receiving member 200 and the second space 180. Also, the first receiving member 200 and the second space 180 is kept open in order to collect the platelet rich plasma remaining in the second space into the first receiving member 200 after the subsequent filtration. Ultimately, a two-way valve 150 may be used in place of the three-way valve 150, and the first receiving member 200 may be mounted on the inlet portion 130 without using a valve.

[0079] For obtaining blood plasma, for example, 9 portions of whole blood is mixed with 1 portion of an anticoagulant, and the mixture is removed of red blood cells through centrifugal separation to extract about 4 to 5.5 portions of blood plasma. It is of course possible to extract a larger amount of the blood plasma by mixing a larger quantity of whole blood and a larger quantity of an anticoagulant and then performing extraction of the blood plasma through centrifugal separation and removal of red blood cells.

[0080] Also, this step S20 may further include a step S22 of receiving air in the second receiving member 210 and then mounting the second receiving member 210 on the membrane filter unit 100. In this regard, the second receiving member 210 may be mounted on the inlet portion 130 formed on the other side of the body 110 via the three-way valve 150, which can be manipulated to open or close the second space 180. The mounting step S22 may be carried out right before the second collecting step S50 described later, or the second collecting step S50 may involve injecting external air into the second space 180, while the mounting step S22 is excluded.

[0081] When the blood plasma is injected into the second space 180, the three-way valve 150 is manipulated to open the inlet portion 130 of the second receiving member 210 to the exterior and thereby to exhaust the air of the membrane filter unit 100. In addition, when a com-

ponent having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 is collected into the first receiving member 200 after the filtration, the second receiving member 210 is mounted on the inlet portion 130 and the three-way valve 150 is manipulated to close the second space 180 of the membrane filter unit 100 from the exterior and allow the second space 180 to open into the second receiving member 210. It is therefore possible to mount the second receiving member 210 and the inlet portion 130 without a two-way valve or another valve other than the three-way valve 150.

[0082] The step S20 may further include a step S23 of moving the piston 311 in one direction by using the pressurizing means 300, that is the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby injecting the blood plasma into the second space 180. In this regard, the pressure that the pressurizing means 300 applies to inject the blood plasma into the second space 180 is in a predetermined pressure range equal to the permissible internal pressure of the filter 120 of the membrane filter unit 100 or below. In the case when the permissible internal pressure of the filter 120 is 500 mmHg, the load internal pressure of the filter 120 during the filtration is in the range of 300 mmHg to 450 mmHg, that is, approximately 60 to 90 %. And, the injection rate for the pressurizing means 300 injecting the blood plasma into the second space 180 is within the range that allows the platelets to settle down in the blood plasma injected in to the second space 180 and enables the continuous injection of the blood plasma while the platelets settle down. The injection pressure and the injection rate can be regulated under the control of the power source 310 and the decelerator 330. When the power source 310 is a motor, the decelerator 330 controls the motor velocity (rpm) of the motor to adjust the injection pressure and the injection rate.

[0083] When the injection pressure is 1,200 kg, for example, the pressure per unit area of the filter 120 in consideration of the gravity is $1,200\text{kg/s}^2 = 0.5\text{kg/cm}^2$, which can be applied to calculate the injection pressure and the injection rate.

[0084] As the blood plasma is injected, the air in the membrane filter unit 100 is exhausted through the three-way valve 150 on the side of the second receiving member 210.

[0085] When the blood plasma is completely injected, the pressure in the membrane filter unit 100 is dropped in a predetermined period of time after the completion of the injection, in step S30. This can activate the settlement of the platelets more by reducing the pressure in the filter 120 of the membrane filter unit 100 and completely exhaust the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 in the second space 180 and temporarily held in the first space 170 through the outlet portion 140.

[0086] In this regard, as a predetermined quantity of

the blood plasma remains in the first receiving member 200 at the time when the injection of the blood plasma is completed, the first plunger 202 stops at a specific position. This is to remain a predetermined quantity of the blood plasma in the first receiving member 200. For extracting 5 portions of platelet rich plasma, for example, about 3 portions of the component having a particle diameter equal to or larger than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 is mixed with about 2 portions of the blood plasma remaining in the first receiving member 200. Accordingly, a defined amount of the platelet rich plasma can be obtained by mixing a defined amount of the component having a particle diameter equal to or greater than the predetermined particle diameter which is obtained through filtration with the membrane filter unit 100 and a defined amount of the blood plasma remaining in the first receiving member 200. The amount of the blood plasma remaining in the first receiving member 200 can be determined based on the amount of the component obtained through the membrane filter unit 100, or the amount of the component obtained through the membrane filter unit 100 can be determined based on the amount of the blood plasma remaining in the first receiving member 200.

[0087] Contrarily, it is possible to obtain no more than the platelet rich plasma filtered through the membrane filter unit 100 by moving the first plunger 202 to a threshold moving position, stopping it and then injecting all the blood plasma of the first receiving member 200 into the membrane filter unit 100.

[0088] Of course, the moving and stop motions of the first plunger 202 are carried out by the movement of the piston 311 mounted on the first plunger 202, and the piston 311 is moved by the power source 310.

[0089] Subsequently, a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit 100 is first collected into the first receiving member 200, in step S40. In this regard, when the power source 310 forces the piston 311 to make a back motion and the first plunger 202 makes a back motion, most of the component having a particle diameter equal to or larger than the predetermined particle diameter in the second space 180 of the membrane filter unit 100 flows into the first receiving member 200. Here, the direction-diverting switch 350 is manipulated for the back motion of the piston 311.

[0090] Finally, air is injected into the membrane filter unit 100 to collect the remaining component having a particle diameter equal to or larger than the predetermined particle diameter into the first receiving member 200, in step S50. For this purpose, the three-way valve 150 of the second receiving member 210 is manipulated to make the second receiving member 210 open into the second space 180, and then the second plunger 212 is moved to inject the air in the second receiving member 210 into the second space 180, thereby forcing all the

component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 to flow into the first receiving member 200. It is of course possible to repeat the step S50 in order to completely flow the component having a particle diameter equal to or greater than the predetermined particle diameter into the first receiving member 200.

<Second Method>

[0091] FIG. 6 is a flow chart showing a second extraction method for concentrated plasma using the extracting device of FIG. 2. The second method according to the present invention is a method of collecting a component having a particle diameter equal to or larger than the predetermined particle diameter without using the second receiving member 210. The second method is similar to the first method on the whole, except for a little difference in the steps. The steps of the second method the same as or similar to the steps of the first method are mentioned as the common content and described briefly under necessity.

[0092] Firstly, the membrane filter unit 100 is fixed in the upright position, in step S10. The step S10 is as defined in the first method.

[0093] Subsequently, the valve 150 mounted in the opposing side of the first receiving member 200 and open into the second space 180 is closed, and the blood plasma is injected into the membrane filter unit 100 and passed through the filter while the platelets are allowed to settle down, in step S20. As the valve 150 is closed, the second space 180 opens into the exterior through the outlet portion 140, so that the first plunger 202 of the first receiving member 200 is pressurized under the same pressure of the first method or the stronger pressure to inject the blood plasma into the second space 180. The valve 150 may be a three-way valve, but preferably a two-way valve because the second receiving member 210 is excluded.

[0094] Accordingly, the step S20 includes the step S21 of mounting the first receiving member 200 on the membrane filter unit 100 and the step S23 of moving the piston 311 in one direction by the power source 310 to move the first plunger 202 of the first receiving member 200 and thereby to inject the blood plasma into the second space 180, but it excludes the step S22 of mounting the second receiving member 210 on the membrane filter unit 100.

[0095] As the second space 180 is mostly closed, an air layer is formed on the opposite side to the first receiving member 200 in the second space 180 while the blood plasma is injected, and the air layer prevents the blood plasma from penetrating above a predetermined height. This can force the component having a relatively high force of adhesion such as platelets to remain below a predetermined height and limit the range of adsorbing the components of the blood plasma onto the filter 120

to the maximum.

[0096] Of course, the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter 120 is exhausted through the outlet portion 140 during the filtration.

[0097] Subsequently, it waits for a predetermined period of time after completion of the injection of the blood plasma and then the pressure in the membrane filter unit 100 is dropped, in step S30. The step S120 is also the same as defined in the first method.

[0098] Subsequently, the outlet portion 140 is blocked to close the second space 180 and then move the first plunger 202 of the first receiving member 200 back, thereby forming a vacuum pressure in the membrane filter unit 100, in step S31. In other words, when the outlet portion 140 is blocked, the second space 180 is completely closed, with the valve 150 closed. At this time, the power source 310 forces the piston 311 to make a back motion and moves the first plunger 202 back, so a strong vacuum pressure is formed in the membrane filter unit 100.

[0099] Finally, the valve 150 is momentarily opened to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space 180 into the first receiving member 200 all at once, in step S40. By part of the air momentarily introduced, the components adsorbed onto the filter 120 are released from the filter 120 and flow into the first receiving member 200.

[0100] This decompression method has an advantage that the components adsorbed onto the filter 120 during the filtration can be released from the filter 120 to the maximum. It is of course possible to repeat the steps S31 and S40 in a manual, semi-automatic, or automatic manner, in which case the operation of the valve 150 can be controlled through the controller in such a manner of controlling a solenoid valve.

[0101] The above-described first and second methods are applied to extract concentrated plasma from the blood plasma. In this regard, the concentrated plasma extracted according to the present invention has a platelet count about 4 to 5 times higher than the platelet rich plasma obtained by the conventional method using the centrifugal separation. A comparison between the concentrated plasma of the present invention and the whole blood is given in Table 1.

[Table 1]

Whole blood	Platelet rich plasma
Platelet count	4 to 11-fold
Protein count	2 to 4-fold
Fibrinogen count	3 to 5-fold
White blood cell count	3 to 5-fold
Red blood cell count	0.2 to 0.4-fold

[0102] Particularly, the blood plasma is changed into a gel and used for many applications. In the conventional method of making the blood plasma containing an anti-coagulant into a gel, bovine thrombin or collagen is added to the blood plasma. But, the bovine thrombin is a substance extracted from livestock and thus possibly contains a component harmful to the human body (e.g., mad cow disease factor, etc.).

[0103] Accordingly, the present invention repeats the filtration of the blood plasma using a membrane filter, more preferably adds calcium to promote the conversion of prothrombin into thrombin as the first step of the blood coagulation mechanism and thereby to form a large quantity of thrombin from the prothrombin in the blood plasma. Such a large quantity of thrombin serves as a factor to convert fibrinogens into fibrin monomers and is enough to form a large quantity of fibrin monomers. Finally, the fibrin monomers form fibrin clots and the platelet rich plasma is extracted in the form of a gel and thus can be used for various use purposes instead of fibrin glue.

[0104] As described above, those skilled in the art will appreciate that the present invention described herein is susceptible to variation other than those specifically described without changing its technical conception and essential features. Therefore, it should be understood that the foregoing description of preferred embodiments of the present invention has been presented for purposes of illustration and not intended to limit the scope of the present invention.

[0105] It should also be understood that the scope of the present invention is defined by the scope of the following claims other than the detailed description and construed to include all the variations and modifications derived from the meanings and scope of the claims and their equivalents.

100: membrane filter unit

110: body

120: filter

130: inlet portion

140: outlet portion

150: valve

160: fixing member

170: first space

180: second space

200: first receiving member

201: first receiving portion

202: first plunger

210: second receiving member

211: second receiving portion

212: second plunger

300: pressurizing means

310: power source

311: piston

320: controller

330: decelerator

340: adaptor

350: direction-diverting switch

Claims

1. A device for extracting concentrated plasma, which is to extract concentrated plasma, the device comprising:
 - a membrane filter unit (100) for isolating a component based on a predetermined particle diameter from blood plasma; and
 - a first receiving member (200) for providing a predetermined injection rate and a predetermined injection pressure to inject the blood plasma into the membrane filter unit (100) and let thereby platelets in the blood plasma settle down by gravity.
2. The device for extracting concentrated plasma as claimed in claim 1, further comprising:
 - a pressurizing means (300) mounted in connection to the first receiving member (200) to provide the injection rate and the injection pressure of the blood plasma.
3. The device for extracting concentrated plasma as claimed in claim 2, wherein the pressurizing means (300) comprises:
 - a piston 311 moving relative to the membrane filter unit (100) to inject the blood plasma in the first receiving member (200) into the membrane filter unit (100); and
 - a power source (310) mounted to induce the movement of the piston (311).
4. The device for extracting concentrated plasma as claimed in claim 3, wherein the power source (310) limits the moving distance of the piston (311) to remain part of the blood plasma in the first receiving member (200) for a predetermined period of time after the time that the injection of the blood plasma into the membrane filter unit (100) is completed.
5. The device for extracting concentrated plasma as claimed in claim 3 or 4, wherein the power source (310) maintains the piston (311) at a position for the predetermined period of time after the time that the movement of the piston (311) is completed.
6. The device for extracting concentrated plasma as claimed in claim 3, wherein the pressurizing means (300) further comprises:
 - an adaptor (340) for intermediating a coupling of a first plunger (202) mounted in the first receiving member (200) and the piston (311) to inject the blood plasma in the first receiving member (200) into the membrane filter unit
- (100); and
- a controller (320) for controlling the operation of the power source (310) to regulate the injection rate and the injection pressure of the blood plasma according to the moving distance and the moving rate of the piston (311) and the first plunger (202).
7. The device for extracting concentrated plasma as claimed in claim 3 or 6, wherein the pressurizing means (300) further comprises:
 - a direction-diverting switch (350) for diverting the moving direction of the piston (311).
8. The device for extracting concentrated plasma as claimed in claim 1, wherein the membrane filter unit (100) comprises:
 - a body 110 having the first receiving member (200) mounted thereon, the body comprising a first and a second inlet portion (130), wherein the air is exhausted through the second inlet portion (130) at one end of the membrane filter unit 100 when the blood plasma flows in through the first inlet portion (130) at the other end of the membrane filter unit (100), and an outlet portion (140) for exhausting a component having a particle diameter equal to or smaller than the predetermined particle diameter passed through the membrane filter unit (100);
 - a hollow filter (120) being mounted in the body (110) and having a second space (180) for receiving the component having a particle diameter equal to or smaller than the predetermined particle diameter which was filtered when the blood plasma of the first receiving member (200) flows in through the first inlet portion (130); and
 - a first space (170) formed between the hollow filter (120) and the body (110) to open into the outlet portion (140) to temporarily receive the component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) and exhaust the same through the outlet portion (140).
9. The device for extracting concentrated plasma as claimed in claim 1 or 8, wherein the membrane filter unit further comprises:
 - a fixing member (160) mounted on the body (110) for arranging the membrane filter unit in the upright position to settle down platelets of the blood plasma flowing into the membrane filter unit under the effect of gravity.
10. The device for extracting concentrated plasma as

claimed in claim 8, further comprising:

a second receiving member (210) being mounted on the membrane filter unit (100) at a predetermined distance from the first receiving member (200) to open into the second space (180) and receiving air.

11. The device for extracting concentrated plasma as claimed in claim 10, wherein the membrane filter unit (100) further comprises a first valve (150) being mounted as an intermediate on a coupling portion between the first inlet portion (130) and the first receiving member (200) and a second valve (150) being mounted as an intermediate on a coupling portion between the second inlet portion (130) and the second receiving member (210), the first valve being arranged to have the second space (180) and the first receiving member (200) open into each other at normal times, and the second valve being arranged to close the second space (180) and the second receiving member (210) when blood plasma is injected into the second space (180), and to open the second space (180) into the second receiving member (210) and inject air in the second receiving member (210) into the second space (180) when a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) is to flow into the first receiving member (200).

12. A method for extracting concentrated plasma, which is to extract concentrated plasma, the method comprising:

a filtering step (S20) of injecting blood plasma into a membrane filter unit (100) to let the platelets settle down by gravity in the blood plasma and thereby remaining a component having a particle diameter equal to or larger than the predetermined particle diameter which has not passed through a filter (120) built in the membrane filter unit (100); and
a step (S40) of collecting the component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the membrane filter unit (100).

13. The method for extracting concentrated plasma as claimed in claim 12, further comprising:

a step (S10) of arranging the membrane filter unit (100) in the upright position to reduce the contact area between the filter (120) in the membrane filter unit (100) and the platelets, before the filtering step (S20).

14. The method for extracting concentrated plasma as

claimed in claim 12, further comprising:

a step (S30) of waiting for a predetermined period of time after the blood plasma is completely injected and reducing pressure in the membrane filter unit (100) after the predetermined period of time to exhaust a component having a particle diameter equal to or smaller than the predetermined particle diameter.

15. The method for extracting concentrated plasma as claimed in claim 12, wherein the filtering step (S20) includes injecting part of the blood plasma into the membrane filter unit (100), wherein the first collecting step (S40) includes collecting both a component, having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the filter, and the remaining blood plasma in one position.

16. The method for extracting concentrated plasma as claimed in claim 15, further comprising:

a second collecting step (S50) of injecting air into the membrane filter unit (100) to collect again both the remaining component having a particle diameter equal to or larger than the predetermined particle diameter and the remaining blood plasma in one position.

17. The method for extracting concentrated plasma as claimed in claim 12, 14, 15, or 16, wherein in all the steps other than the collecting step, first and second spaces (170) and (180) are formed by mounting a filter (120) in a body (110) of the membrane filter unit (100), wherein the second space (180) holds a component having a particle diameter equal to or larger than the predetermined particle diameter which is filtered out from the filter (120) when the blood plasma flows in, the first space (170) temporarily collecting a component having a particle diameter equal to or smaller than the predetermined particle diameter which has passed through the filter (120) to exhaust the component through an outlet portion (140) formed in the body (110) of the membrane filter unit (100).

18. The method for extracting concentrated plasma as claimed in claim 17, wherein the filtering step (S20) further includes a step (S23) of injecting the blood plasma into the second space (180) at a predetermined injection rate and a predetermined pressure to let the platelets settle down by gravity, wherein the injection pressure of the blood plasma is determined to have the range of a load internal pressure imposed on the filter (120) mounted in the membrane filter unit (100) during the filtration is equal to or lower than the permissible internal pres-

sure of the filter (120).

19. The method for extracting concentrated plasma as claimed in claim 18, wherein the injecting step (S23) includes using a pressurizing means (300) to move a first plunger (202) mounted on a first receiving member (200) holding the blood plasma and push the blood plasma, wherein as a power source (310) of the pressurizing means (300) moves a piston (311) to move the first plunger (202) mounted on the piston (311), thereby injecting the blood plasma into the second space 180 at a predetermined injection rate and a predetermined pressure, wherein when part of the blood plasma is injected into the second space (180), the remainder of the blood plasma remains in the first receiving member (200), wherein after filtration, the first plunger (202) is moved back to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space into the first receiving member (200) holding the remaining blood plasma.

20. The method for extracting concentrated plasma as claimed in claim 19, wherein air in a second receiving member (210) mounted on the membrane filter unit (100) is injected into the second space (180) to collect a component having a particle diameter equal to or larger than the predetermined particle diameter and remaining in the second space (180) into the first receiving member (200) holding the remaining blood plasma.

21. The method for extracting concentrated plasma as claimed in claim 20, wherein the first receiving member (200) and the second receiving member (210) are connected to the second space (180), wherein before the second collecting step (S50), a first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and a second valve (150) is manipulated to disconnect the second space (180) from the second receiving member (210), wherein in the second collecting step (S50), the first valve (150) is manipulated to have the second space (180) open into the first receiving member (200) and the second valve (150) is manipulated to have the second space (180) open into the second receiving member (210).

22. The method for extracting concentrated plasma as claimed in claim 14, wherein the filtering step (S20) includes opening a first valve (150) at a side of a receiving member (200) to have the second space (180) open into the first receiving member (200) and closing a second valve (150) mounted on the oppo-

site side of the first receiving member (200).

23. The method for extracting concentrated plasma as claimed in claim 22, wherein in the filtering step (S20), when the blood plasma is injected, an air layer is formed in part of the space of the membrane filter unit (100) to limit the injection height of the blood plasma to a predetermined height or below.

24. The method for extracting concentrated plasma as claimed in claim 22, further comprising:

a step S31 of completely closing the membrane filter unit and forming a vacuum pressure in the membrane filter (100), after the pressure-reducing step (S30).

25. The method for extracting concentrated plasma as claimed in claim 24, wherein the collecting step S40 includes opening the second valve (150) to momentarily supply external air into the membrane filter unit (100) and thereby collecting a component having a particle diameter equal to or larger than the predetermined particle diameter using the air.

26. The method for extracting concentrated plasma as claimed in claim 12, wherein the concentrated plasma becomes gel by repeatedly filtering the blood plasma injected into the membrane filter unit (100) or adding calcium and then repeatedly filtering the blood plasma.

FIG. 1

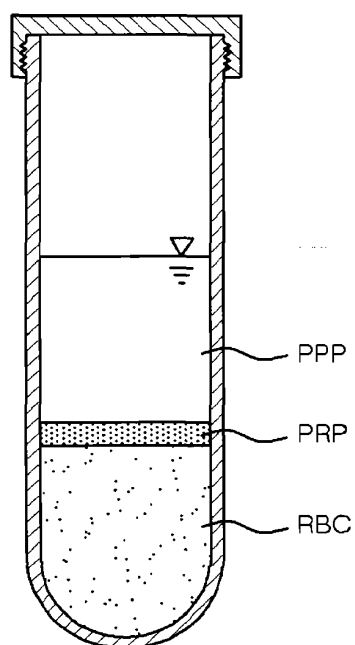


FIG. 2

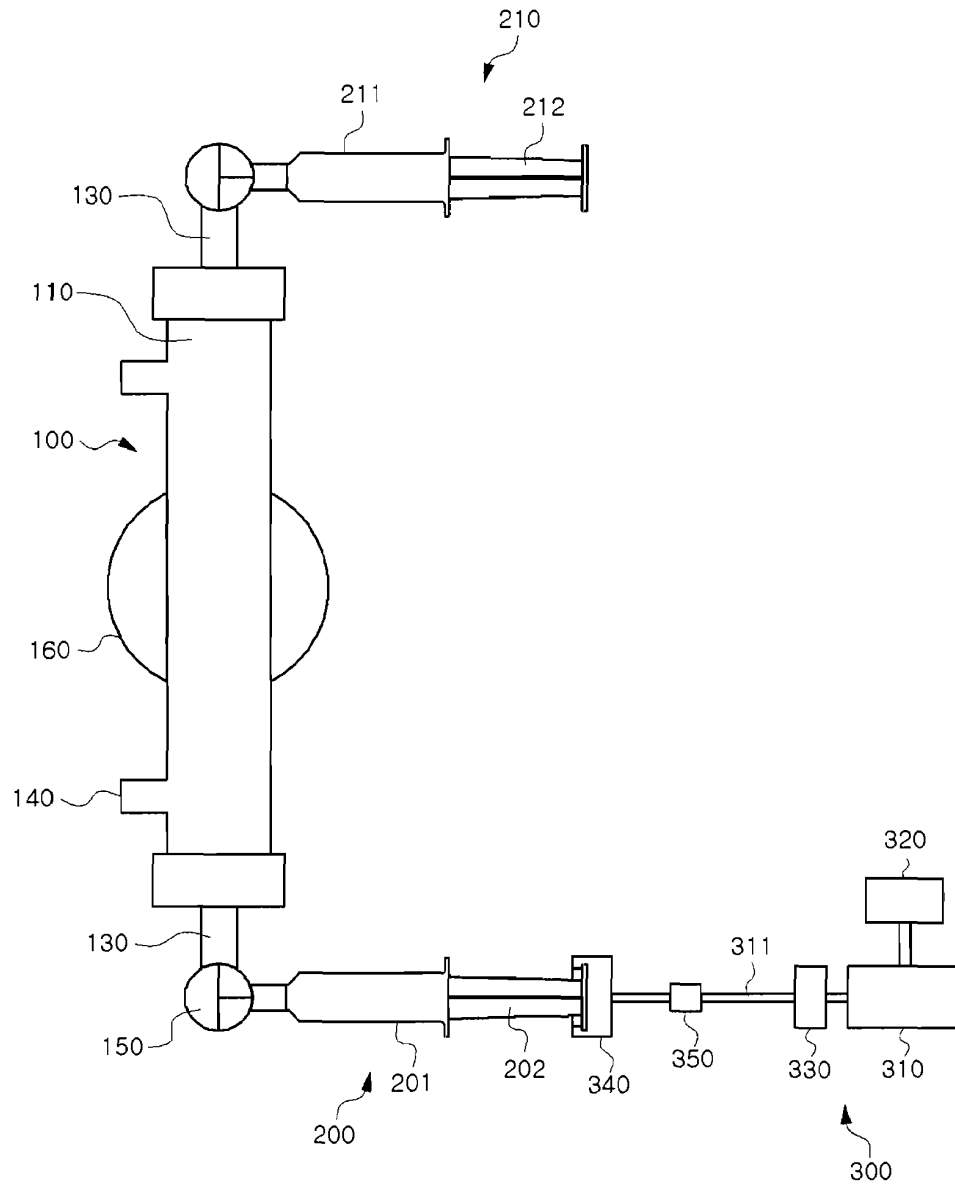


FIG. 3

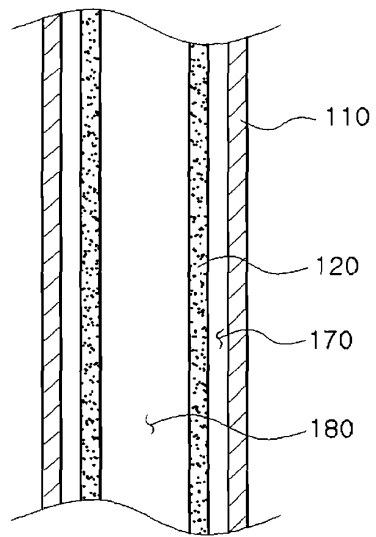


FIG. 4a

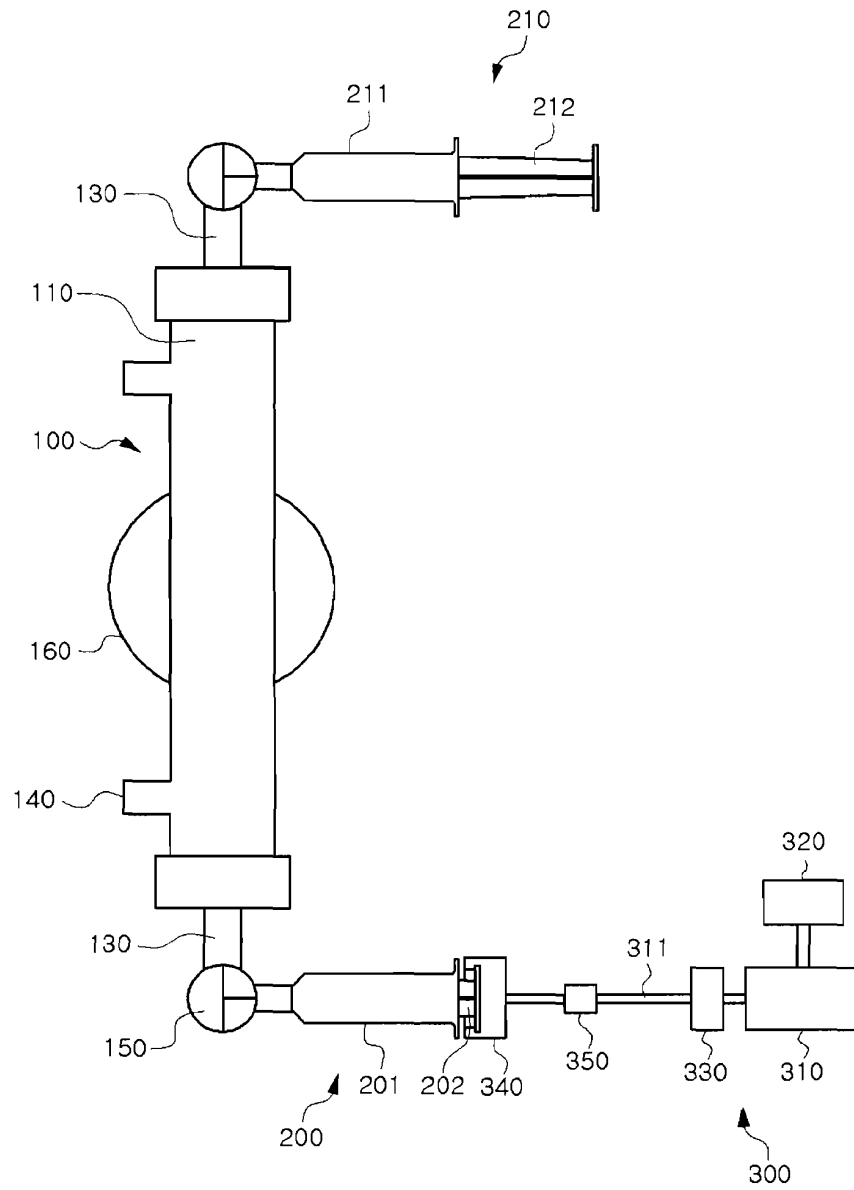


FIG. 4b

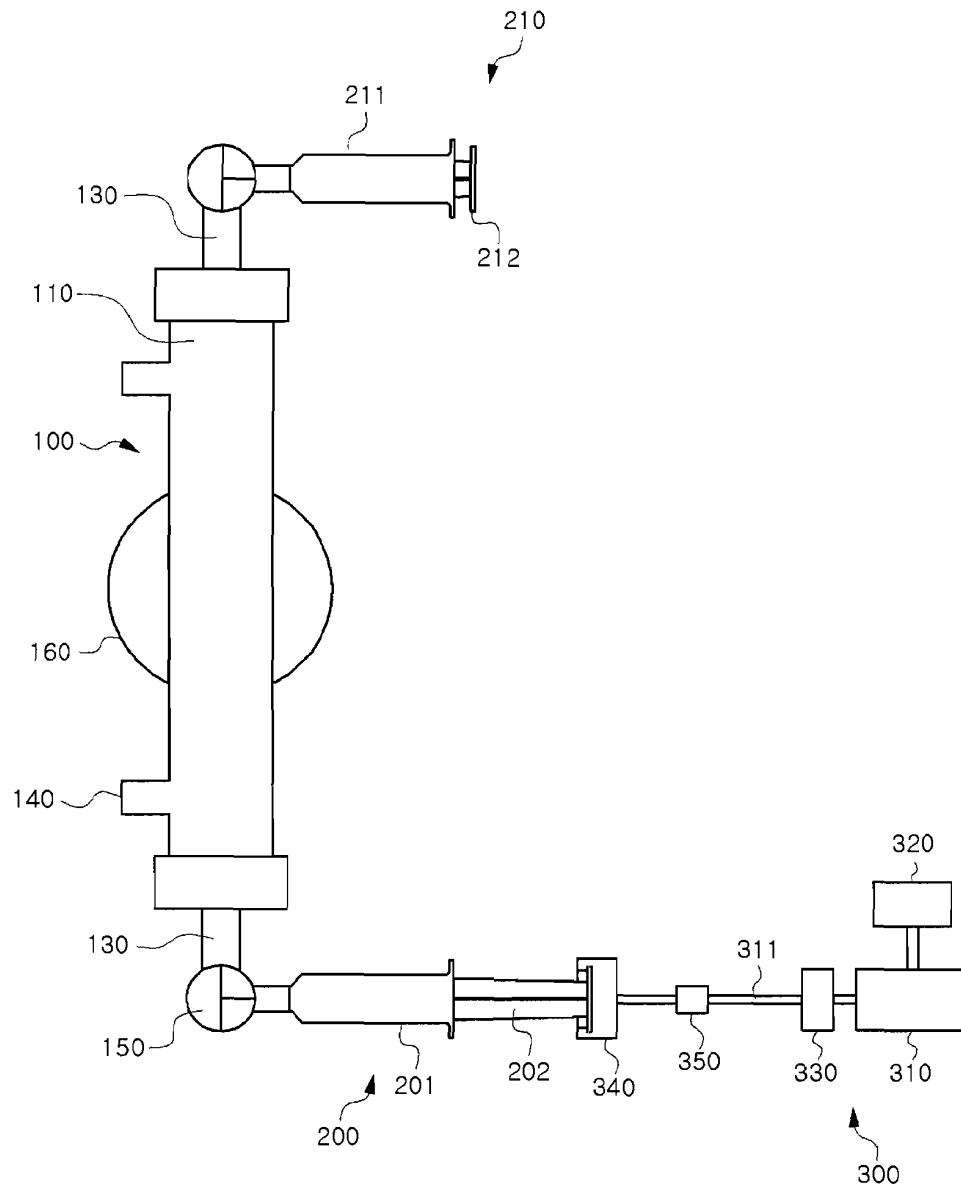


FIG. 4c

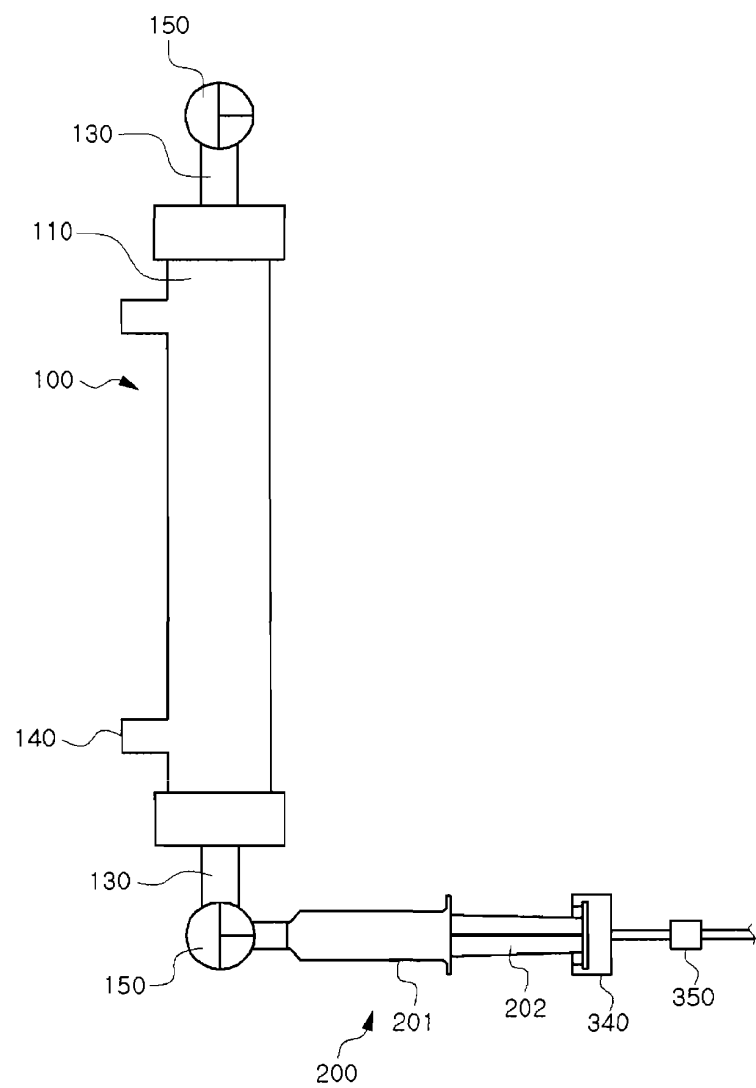


FIG. 5

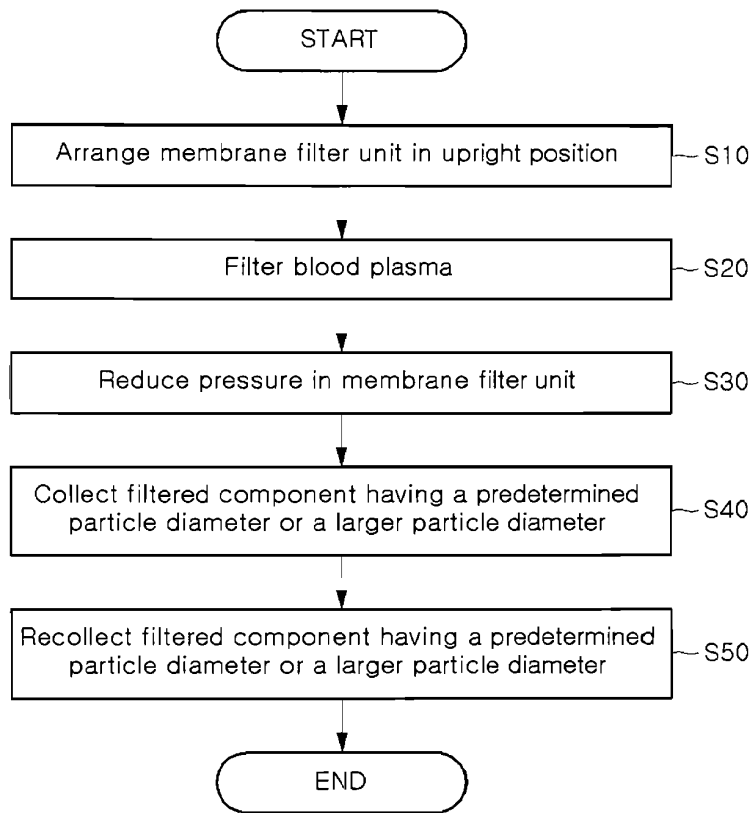
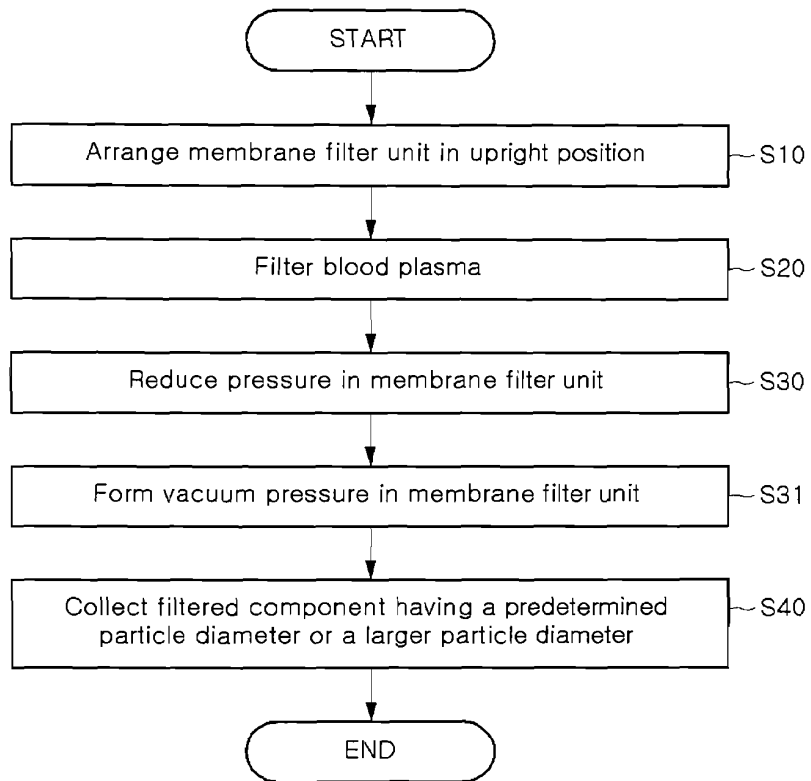


FIG. 6





EUROPEAN SEARCH REPORT

Application Number
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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 6 342 157 B1 (HOOD III ANDREW G [US]) 29 January 2002 (2002-01-29) * column 7, line 1 - line 39 * * column 8, line 29 - line 67 * * figure 3 *	1-26	INV. G01N33/49 A61M1/34 B01D61/14
X	US 4 424 132 A (IRIGUCHI NORIO [JP]) 3 January 1984 (1984-01-03) * column 5, line 30 - column 7, paragraph 17 *	1-26	
A	EP 2 407 245 A2 (GLOTECH CO LTD [KR]; IHM KHI PYO [KR]) 18 January 2012 (2012-01-18) * the whole document *	1-26	
			TECHNICAL FIELDS SEARCHED (IPC)
			G01N A61M B01D
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 23 September 2015	Examiner Baranski, Jörg
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03.02 (P4/C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 14 17 6323

5

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

23-09-2015

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Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 6342157	B1	29-01-2002	US	6010627 A	04-01-2000
			US	6342157 B1	29-01-2002

US 4424132	A	03-01-1984	NONE		

EP 2407245	A2	18-01-2012	CN	102438757 A	02-05-2012
			EP	2407245 A2	18-01-2012
			JP	5725517 B2	27-05-2015
			JP	2013504755 A	07-02-2013
			KR	20110045980 A	04-05-2011
			RU	2011144825 A	10-05-2013
			US	2012053041 A1	01-03-2012
			WO	2011052910 A2	05-05-2011

EPO FORM P0468

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- KR 2010011616010 [0008]
- KR 2010004143610 [0008]



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
18/342,553

RECEIPT DATE / TIME
07/13/2023 06:07:54 PM ET

ATTORNEY DOCKET #
111552.8018.US11

Title of Invention

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 6799

FILED BY J iYoung Anderson

PATENT CENTER # 62439249

FILING DATE -

CUSTOMER # 25096

FIRST NAMED INVENTOR Ben Merritt

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Matthew Williams

Documents

TOTAL DOCUMENTS: 8

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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2023-7-13 IDS SB08 - 111552-8018US11.PDF	35	Information Disclosure Statement (IDS) Form (SB08)	386 KB
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Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

NPL-Gross-Dump the Pump.PDF	4	Non Patent Literature	870 KB
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NPL_ISR_PCT_2023-61256- June-7-2023-8-pages.PDF	8	Non Patent Literature	1063 KB
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FOR_EP2942624.PDF	24	Foreign Reference	1188 KB
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FOR_WO2006029270.PDF	33	Foreign Reference	1157 KB
FOR_WO2006124307.PDF	19	Foreign Reference	2080 KB
FOR_WO2016014955.PDF	63	Foreign Reference	2325 KB
NPL_ISR_WO_PCTUS20236 1256_JUN_07_2023_8pages. PDF	8	Non Patent Literature	3835 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-7-13 IDS SB08 - 111552- 8018US11.PDF	D4FF98CA9AC5AC800719AD9ECC5B5D61F73EAE B1CA2C0C5 21F9EEDE5D4B009432F42697B2A13859FB2B6684EA62B154E2 10350F75E60FA62043ADC704DF0C905
NPL-Gross-Dump the Pump.PDF	D44985D30C015BE8DA101967568EDF70598C9DCC517B882F1 524CC5F8D5C8C53620135568E11D3A8E76C94DABDD42BAD C 78DE5603483BF94B00DA3679A300F1D
NPL_ISR_PCT_2023-61256- June-7-2023-8-pages.PDF	E29F558402CAA5ECA7B480DBF767FC910107364FF8EB3919C 86E39BC20664311EDA23D81B18626667115B85F0FF8707387E 626478C646A16AA39EB2CD5DE7AAA
FOR_EP2942624.PDF	76F180E3DB96728ABCFFD31B77A2404E0AC8EA38F6420ED87 9A30A22CD22FA1628FB338AD6869D29C985D62AFB79F29288 2F89866AD893AB9B9EB39BC5CE38DF
FOR_WO2006029270.PDF	9F9FCC67AFD589CE61E4B384802B8F1B3B2118E927157C959 323391A302F028ADA8961E7CC81A93CDF03C5DD57AD1D8FB 16AE710689466AD8D1ED27132ACD968
FOR_WO2006124307.PDF	4CA9E275B28C639DF92082C698747D391EB4FEFEEA1BB6C9 B742A1F4DE7964B77944A82E842650ED0069421D200988267A 5E6CE83FEC33F777AC3CCFF6120555

FOR_WO2016014955.PDF	DE12ACD76BAE4B0E156B6F9D382CAEBE3E6243ED877F0352 56811EF33F0A9463A0204B3777321B5207E9E06058DD462E99 A3EA229302CDF42B2A63C4E5792EF2
NPL_ISR_WO_PCTUS2023612 56_JUN_07_2023_8pages.PDF	B6488599ED52A352BA8B312D7D92B68C79580FB669FA073F5 A5F3AB3439258CFE6E444A59296AB61409AAFD58060C1796B4 1828CA2BC9C77D2027492AAC95F68

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew S. Williams Perkins Coie LLP P.O. Box 1247 Seattle, WA 98111-1247 United States Of America
RECEIVED PATENT DOCKETING JUN 12 2023
PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	JUN 07 2023
Applicant's or agent's file reference 111552-8035WO00	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)
Applicant INARI MEDICAL, INC.	

1. ☒	The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46). When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report. How? Directly to the International Bureau preferably through ePCT, or on paper to: The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland For more detailed instructions, see the <i>PCT Applicant's Guide, International Phase</i>, paragraphs 9.004 -- 9.011.
2. ☐	The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐	With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices. ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Reminders	The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3). Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the <i>PCT Applicant's Guide, National Chapters</i>. Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the <i>PCT Applicant's Guide, International Phase</i>, paragraphs 8.006-8.032.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1480, Alexandria, Virginia 22313-1480 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
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Form PCT/ISA/226 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 111552-8035W000		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US23/61256	International filing date (day/month/year) 25 January 2023 (25.01.2023)	(Earliest) Priority Date (day/month/year) 31 January 2022 (31.01.2022)	
Applicant INARI MEDICAL, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

I. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. 1.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 3A
- ☒ as suggested by the applicant.
- ☐ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/61258

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 1/00 (2023.01)

ADD. A61B 17/22; A61M 25/00 (2023.01)

CPC - INV. A61M 1/84; A61M 25/0043; A61M 25/0045; A61M 25/005

ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 25/0073; A61M 2206/16; A61M 2206/20

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2016/0030706 A1 (ANGIODYNAMICS INC.) 04 February 2016; figures 4, 8b; paragraphs 0008, 0009, 0030, 0036, 0038, 0039; abstract; claim 3	1-13, 15-21 --- 14
X	US 2016/0135829 A1 (ANGIODYNAMICS INC.) 19 May 2016; figures 2a-4c, 7; paragraphs 0037, 0049	22-24
Y	US 2006/0264905 A1 (ESKRIDGE ET AL.) 23 November 2006; paragraphs 0005, 0027	14
A	US 5,244,619 A (BURNHAM) 14 September 1993; entire document	1-24
A	US 2017/0021130 A1 (DYE) 26 January 2017; entire document	1-24

☐ 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 doubt 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

"Z" document member of the same patent family

Date of the actual completion of the international search

24 April 2023 (24.04.2023)

Date of mailing of the international search report

JUN 07 2023

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2022)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Matthew S. Williams Perkins Coie LLP P.O. Box 1247 Seattle, WA 98111-1247 United States Of America
RECEIVED PATENT DOCKETING JUN 12 2023 PERKINS COIE LLP

Date of mailing (day/month/year)	JUN 07 2023
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Applicant's or agent's file reference 111552-8039WC00		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US23/81256	International filing date (day/month/year) 25 January 2023 (25.01.2023)	Priority date (day/month/year) 31 January 2022 (31.01.2022)	
International Patent Classification (IPC) or both national classification and IPC IPC - INV. A61M 1/00 (2023.01) ADD. A61B 17/22; A61M 25/00 (2023.01) CPC - INV. A61M 1/04; A61M 25/0043; A61M 25/0045; A61M 25/005 ADD. A61B 2017/22079; A61B 2217/005; A61M 25/0023; A61M 2025/0073; A61M 2206/16; A61M 2206/20			
Applicant INARI MEDICAL, INC.			

1. This opinion contains indications relating to the following items: ☒ Box No. I Basis of the opinion ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application	
2. FURTHER ACTION <i>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(h) that written opinions of this International Searching Authority will not be so considered.</i> <i>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</i> For further options, see Form PCT/ISA/220.	

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 24 April 2023 (24.04.2023)	Authorized officer Shane Thomas PCT Help Desk Telephone No. 571-272-4300
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Form PCT/ISA/237 (cover sheet) (July 2022)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61258

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(s) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).

3. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:

- a. ☐ forming part of the international application as filed.
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2016/1256

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	14	YES
	Claims	1-13, 15-24	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 7-10, 15, and 17-21 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics, Inc. US 2016/0030706 A1 (AngioDynamics).

As to claim 1, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4).

As to claim 2, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove extends from the distal terminus to the proximal terminus (para [0036]; claim 3).

As to claim 3, AngioDynamics teaches the aspiration catheter of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the at least one groove revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009]; para [0030]).

As to claim 7, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove has a spiral shape (abstract; para [0009]; para [0030]).

As to claim 8, AngioDynamics teaches the aspiration catheter of claim 1 wherein the at least one groove comprises a plurality of grooves (fig. 4; abstract; para [0009]; para [0030]).

As to claim 9, AngioDynamics teaches the aspiration catheter of claim 8 wherein the plurality of grooves are equally spaced apart about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 10, AngioDynamics teaches the aspiration catheter of claim 8 wherein the lumen extends along a longitudinal axis, and wherein the plurality of grooves revolves circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (para [0036]; claim 3).

As to claim 15, AngioDynamics teaches an aspiration catheter (30), comprising: a proximal terminus; a distal terminus; and an inner surface defining a lumen extending along a longitudinal axis (para [0009]), wherein the inner surface includes a plurality of grooves formed therein (channels 33), wherein the grooves extend at least partially between the distal terminus and the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the distal terminus and the proximal terminus (abstract; para [0009]; para [0030]).

As to claim 17, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b).

As to claim 18, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend to the distal terminus (para [0036]; claim 3).

As to claim 19, AngioDynamics teaches the aspiration catheter of claim 15 wherein the grooves extend entirely between the distal terminus and proximal terminus (para [0036]; claim 3).

As to claim 20, AngioDynamics teaches a system for removing material from within a lumen of a human patient, the system comprising: an aspiration catheter (30) configured to be positioned at a treatment site proximate to the material within the lumen, wherein the aspiration catheter comprises a proximal terminus; a distal terminus; and an inner surface defining a lumen (para [0009]), wherein the inner surface includes at least one groove formed therein (channels 33) and that extends from the distal terminus at least partially toward the proximal terminus (fig. 4); a tubing assembly fluidly coupled to the catheter (connected to a port or syringe; para [0036], [0039]) and including a fluid control device (power aspiration para [0008] or syringe 110); and a pressure source fluidly coupled to the tubing assembly and configured to generate negative pressure (power aspiration para [0006] or syringe 110, para [0039]), wherein the fluid control device is movable

Continued in Supplemental Box.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US23/61256

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-Continued From Box V. 2. Citations and Explanations-.

between (a) a first position in which the pressure source is fluidly connected to the aspiration catheter via the tubing assembly and (b) a second position in which the pressure source is fluidly disconnected from the aspiration catheter (the catheter is fully capable of being connected and disconnected from pressure source).

As to claim 21, AngioDynamics teaches the system of claim 20 wherein the lumen extends along a longitudinal axis, wherein the at least one groove includes a plurality of grooves (fig. 4), wherein the grooves are equally spaced about a circumference of the inner surface (fig. 4; see cross-section in fig. 8b), wherein the grooves extend at least partially from the distal terminus to the proximal terminus (fig. 4), and wherein the grooves revolve circumferentially about the longitudinal axis between the proximal terminus and the distal terminus (abstract; para [0009], para [0030]).

Claims 22-24 lack novelty under PCT Article 33(2) as being anticipated by AngioDynamics US 2016/0135829 A1 (AngioDynamics2).

As to claim 22, AngioDynamics2 teaches a method for removing material from within a lumen of a human patient, the method comprising: positioning a distal portion of an aspiration catheter proximate to the material within the lumen (figs. 2a-4c), wherein the aspiration catheter includes an inner surface having at least one groove formed therein (para [0037]), and wherein the at least one groove extends from a distal terminus of the aspiration catheter at least partially toward a proximal terminus of the aspiration catheter (para [0037]); coupling a pressure source to the aspiration catheter via a fluid control device (para [0049]), wherein (a) opening of the fluid control device fluidly connects the pressure source to the aspiration catheter and (b) closing of the fluid control device fluidly disconnects the pressure source from the aspiration catheter; activating the pressure source to generate a vacuum while the fluid control device is closed; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the material into the aspiration catheter (it is well known that powering on a vacuum pump will operate/activate will connect a vacuum, and powering off the pump will close disconnect a vacuum).

As to claim 23, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove defines a leak path past the clot material when the clot material is aspirated into the aspiration catheter (channels form paths).

As to claim 24, AngioDynamics2 teaches the method of claim 22 wherein the at least one groove generates a helical flow pattern in the lumen when the clot material is aspirated into the aspiration catheter (para [0037], [0039], fig. 7).

Claims 4-6, 11-13, and 16 lack an inventive step under PCT Article 33(3) as being obvious over AngioDynamics.

As to claims 4-6, AngioDynamics teaches the aspiration catheter of claim 3. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 11-13, AngioDynamics teaches the aspiration catheter of claim 10. It should be noted that AngioDynamics fails to specifically teach the plurality of grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.05 times or more per inch; between about 0.13-0.15 times per inch; or more than about 0.13 times per inch depending on the desired effect during a procedure (para [0035]).

As to claims 15, AngioDynamics teaches the aspiration catheter of claim 15. It should be noted that AngioDynamics fails to specifically teach the at least one groove revolves between about 0.13-0.15 times per inch. AngioDynamics does teach that the pitch of the grooves can be used to optimize flow rate depending of the procedure (para [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the grooves revolves about 0.13-0.15 times per inch, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the grooves of AngioDynamics to revolve about 0.13-0.15 times per inch depending on the desired effect during a procedure (para [0035]).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over AngioDynamics in view of Eskridge et al. US 2006/0264905 A1 (Eskridge).

As to claim 14, AngioDynamics teaches the aspiration catheter of claim 1. It should be noted that AngioDynamics fail to teaches wherein the catheter further comprises: an inner liner having the inner surface, wherein the at least one groove is formed in the inner liner; a braid of wires over the inner liner; a wire coiled over the inner liner; and an outer sheath over the braid, the wire, and the inner liner. AngioDynamics does teach the desire to prevent pinching or collapsing of the catheter when negative pressure is applied (para [0007]).

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Continuation of:

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Eskridge teaches multi-layered catheter construction is well known in the art, and it is well known to combinations of liners, coils, and braids to prevent kinks (para [0005], [0027]). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of AngioDynamics to include the liner, coil, and braid of Eskridge to prevent pinching or collapsing of the catheter by increasing stiffness while still providing flexibility (para [0005], [0027]).

Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

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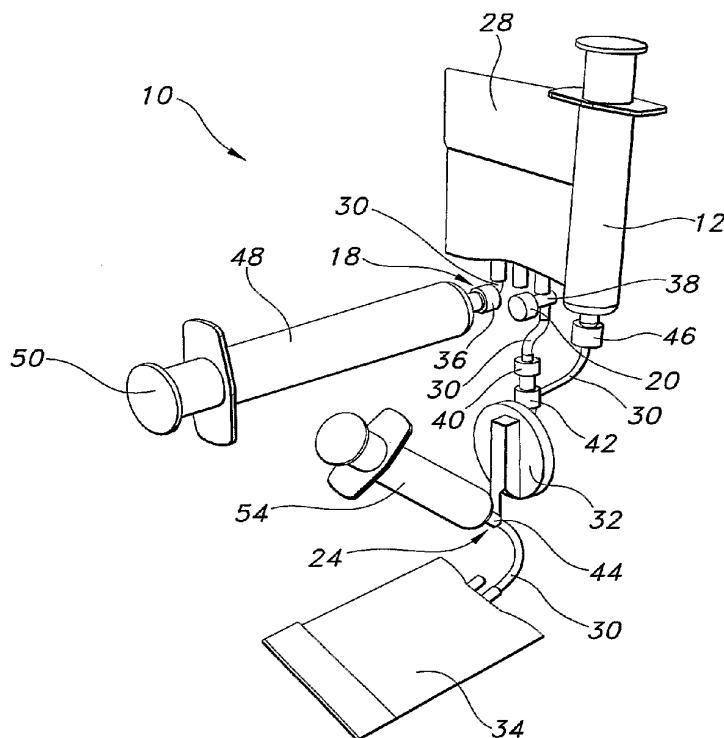
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(54) Title: METHODS AND DEVICES FOR STERILE FIELD TRANSFER



(57) Abstract: Devices and methods for facilitating the transfer of at least a component of a material into a sterile vessel (12). Such devices and methods may utilize a housing (14) at least partially enclosing the sterile vessel to facilitate maintaining the sterility of the vessel before and during the transfer of the at least a component of a material into the sterile vessel.

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METHODS AND DEVICES FOR STERILE FIELD TRANSFER

RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent Application Serial No. 60/607,631, entitled "Sterile Field Transfer Method and Design" filed September 7, 2004, the entire contents of which are hereby incorporated by this reference.

RELATED FIELDS

Embodiments of the present invention relate to methods and devices for transferring at least a component of a material into a sterile vessel for use in a sterile field.

BACKGROUND

It is often necessary to ensure that items used in a sterile field, such as an operating room, research & development facility, or other sterile environment, are themselves sterile. Instruments, devices, containers, implants and other items intended for use in the sterile field may require sterilization and may need to be maintained in a sterile condition. Items that are non-sterile, or that potentially have contacted other non-sterile items or non-sterile persons (such as doctors, technicians or nurses who have come into contact with non-sterile items), may be unacceptable for use in the sterile field. Accordingly, doctors, nurses, technicians and other individuals working in or around sterile fields must follow strict guidelines and procedures for ensuring the sterility of items brought into and/or used in the sterile field. Some of the current sterilization procedures and guidelines, however, are undesirable, burdensome and inefficient.

For example, typical procedures for collecting and transporting blood platelets into a sterile field may be undesirable, as those procedures may require the transfer of the platelets between a number of different containers and devices. Typically, the nurse, technician, doctor or other individual collects a blood sample in a syringe. Next, he or she transfers the blood into a centrifuge. The centrifuge processes the blood to concentrate the blood platelets. Next, the

concentrated blood platelets are collected into another syringe and subsequently transferred into a sterile cup. The sterile cup is finally brought into the sterile field where it can be drawn into a sterile syringe. Such a technique is undesirable, as it requires the blood and blood platelets to be transferred multiple times from vessel to vessel in a manner that is inefficient and subject to spillage or even accidental contamination.

Other procedures, techniques and guidelines for ensuring the sterility of items used in sterile fields may also be undesirable, burdensome and inefficient.

SUMMARY

Embodiments of the present invention provide safe and efficient methods and devices for transferring a material or a component of a material from a non-sterile vessel or potentially non-sterile vessel into a sterile vessel, while maintaining the sterility of the sterile vessel. Embodiments of the present invention may be suitable for transferring a wide variety of materials or material components into a sterile vessel, including, but not limited to, blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, polymers, composite materials, nanomaterials, or any other material or material component that is intended for use in a sterile field. Devices according to various embodiments of the present invention may also process the materials or material components introduced into the device prior to or during transfer into the sterile vessel. Exemplary processes include, but are not limited to, filtration to separate larger components of a material from smaller components (e.g, filtering blood to separate the platelets from other blood components), mixing materials together, separating materials, reacting various materials together, instrument fabrication, implant fabrication, sterilization or any other process that may be done to a material or a material component prior to use in a sterile field. In other embodiments, devices of the present invention do not process the materials introduced into them at all, but merely facilitate the material transfer into the sterile vessel without affecting the sterility of the sterile vessel.

Devices of the present invention may include a sterile vessel and a housing at least partially enclosing the sterile vessel. The device housing may enclose the sterile vessel to protect the vessel from direct contact with potentially non-sterile persons and items, which could potentially affect the sterility of the sterile vessel and prevent use of the vessel in the sterile field. In some embodiments, the housing may include a cover that limits access to the sterile vessel until the cover is removed or opened. In other embodiments, such a cover is unnecessary.

Devices according to the present invention may also include a material input accessible from outside the housing. The material input may facilitate the introduction of a material into the device, which eventually may be transferred by the device (or a component of the material may be transferred by the device) into the sterile vessel. In some embodiments, the material input interacts with a non-sterile syringe or other vessel external to the device. In some embodiments, the material input is associated with a conduit within the device that conveys the material to various internal components of the device (such as a filter) and to the sterile vessel. In other embodiments, the conduit is integral with the material input and conveys the material directly into the sterile vessel.

Some embodiments of the present invention may also include internal components, such as filters or other components, for processing the inputted material. In some embodiments, the device may also include additional material inputs and/or internal components for introducing and/or processing additional materials in the device. The additional materials introduced may facilitate various processes of the device and/or may facilitate the movement of other materials (or components thereof) within and between various internal components of the device. In other embodiments, the device does not include such components and merely conveys the material directly into the sterile vessel.

In some embodiments, the device is disposed of after use and is made with relatively inexpensive materials.

STATEMENT OF THE INVENTION

Accordingly, embodiments of the present invention provide for a device for facilitating the transfer of at least a component of a material into a sterile vessel, characterized in that the device comprises: a sterile vessel; a housing at least partially enclosing the sterile vessel; a material input for facilitating the input of a material into the device, the material input accessible from outside the housing; and a conduit for guiding movement of at least a component of the material from the material input to the sterile vessel.

More preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises a cover and wherein moving the cover facilitates accessing the sterile vessel.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the cover is at least temporarily sealed on the device.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the cover comprises a removable cap or a moveable hatch.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises an at least semi-transparent window.

Also even more preferably, embodiments of the present invention provide for a device further characterized in that the housing comprises at least one actuator for actuating at least one valve, the at least one valve for at least partially regulating the movement of the at least a component of a material through the conduit.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a reservoir associated with the conduit.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the reservoir is associated with the material input and receives material from the material input.

Also more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a filter for separating the component from a second component of the material.

Even more preferably, embodiments of the present invention provide for a device further characterized in that the conduit directs the component into the sterile vessel.

Yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second material input for receiving a second material, wherein introduction of the second material into the device facilitates moving the component from the filter to the sterile vessel.

Also yet even more preferably, embodiments of the present invention provide for a device further characterized in that the device comprises a second reservoir for collecting the second component from the filter.

Other embodiments of the present invention provide for a method for facilitating the transfer of at least a component of a material into a sterile field, characterized in that the method comprises: collecting a material into a vessel; transferring the material from the vessel into a device, characterized in that the device comprises: a sterile vessel; and a housing at least partially enclosing the sterile vessel; transporting the sterile vessel into a sterile field; and removing the sterile vessel from the device.

More preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is transported into the sterile field prior to removing the sterile vessel from the device.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the sterile vessel is removed from the device prior to transporting the sterile vessel into the sterile field.

Also more preferably, embodiments of the present invention provide for a method further characterized in that removing the sterile vessel from the device comprises moving a cover of the housing of the device to access the sterile vessel.

Even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises removing the cover from the device.

Also even more preferably, embodiments of the present invention provide for a method further characterized in that moving the cover comprises opening a hatch.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises filtering the material to separate the material into a first component and a second component.

Also more preferably, embodiments of the present invention provide for a method further characterized in that the method comprises disposing of the device.

BRIEF DESCRIPTION OF FIGURES

Figure 1 is a schematic of a device according to a first embodiment of the present invention.

Figure 2 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 3 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 4 is a perspective view of a device according to another embodiment of the present invention, shown without the device's housing.

Figure 5(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 5(b) is a side view of the device of Fig. 5(a).

Figure 6(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 6(b) is a side view of the device of Fig. 6(a).

Figure 6(c) is a rear perspective view of the device of Fig. 6(a).

Figure 7(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 7(b) is a side view of the device of Fig. 7(a).

Figure 8(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 8(b) is a side view of the device of Fig. 8(a).

Figure 9(a) is a perspective view of the exterior of a device according to another embodiment of the present invention.

Figure 9(b) is a side view of the device of Fig. 9(a).

DETAILED DESCRIPTION OF FIGURES

Fig. 1 shows a device 10 in accordance with embodiments of the present invention. In the configuration shown in Fig. 1, device 10 includes a sterile vessel 12, a housing 14 (which includes a cover 16), a material input 18, an actuator 20, a window 22, a second material input 24, a base 26, and a seal 100. In other embodiments, some or all of these features are unnecessary and/or are present in different configurations, positions, orientations, shapes and sizes.

The sterile vessel 12 shown in Fig. 1 is a syringe, however, sterile vessel may be any vessel suitable for receiving materials or components of materials, including test tubes, beakers, vials, IV bags, sample holders, pails, cups, bowls, trays, or gloved hands. Sterile vessel 12 may be sterilized prior to installation in device 10 or sterilized along with the rest of device 10 or components of device 10. Sterile vessel 12 (and other components of device 10 if desired or required) may be sterilized in any suitable procedure or technique, including, but not limited to, gas sterilization or gamma radiation. In other embodiments, it is unnecessary to subject sterile vessel 12 and/or other components of device 10 to a sterilization procedure and/or the sterile vessel may have been maintained in a sterile condition since its manufacture.

The housing 14 shown in Fig. 1 encloses sterile vessel 12. Housing 14 is preferably formed from a plastic, such as polycarbonate, however, housing 14 may be formed from other materials if desired. In some embodiments, it is desirable to form housing 14 (and other components of device 10) from relatively inexpensive materials, as device 10 may be intended to be disposable or intended for "one time use" in some configurations.

Because the housing 14 shown in Fig. 1 encloses sterile vessel 12, the sterility of vessel 12 may be preserved even if device 10 is used in non-sterile fields or comes into contact with non-sterile persons or things. In the embodiment of Fig. 1, the housing 14 (which includes the cover 16 in the configuration shown in Fig. 1) preserves the sterility of vessel 12 until such time as cover 16 is removed or repositioned to allow access to sterile vessel 12 by a sterile nurse, doctor, technician or other individual for use in a sterile field. In some embodiments, a non-sterile individual will remove or reposition the cover 16 and a sterile individual will remove the sterile vessel 12 such that the vessel 12 does not contact non-sterile persons or things and such that the sterile person does not contact the potentially non-sterile housing 14 of device 10. In other embodiments, device 10 may be configured to automatically move the cover 16 or otherwise facilitate access to sterile vessel 12 after the occurrence of one or more events. For instance, in some embodiments, the transfer or completion of transfer of a material into sterile vessel 12 may trigger the device 10 to automatically move the cover 16 or otherwise facilitate accessing vessel 12.

In some embodiments, one person will transport the device 10 into the sterile field and the sterile person will remove the sterile vessel 12. In other embodiments, the sterile person will remove the sterile vessel 12 from the device 10 outside of the sterile field, and then enter the sterile field with the sterile vessel 12.

As shown in Fig. 1, cover 16 is a removable lid. In other embodiments, a cover 16 similar to the one shown in Fig. 1 can be used in conjunction with the devices 10 shown in Figs. 5(a), 5(b), 7(a), 7(b), 8(a), 8(b), 9(a) and 9(b), although the devices 10 shown in these Figures may not necessarily require such a cover in all embodiments. In still other embodiments, such as shown in Fig. 6(c), cover 16 may be a hatch mounted to device 10 in a rotating fashion.

As shown in Fig. 1, cover 16 includes a removable or breakable seal 100 for indicating whether sterile vessel 12 has been previously accessed or tampered with (indicating a potential loss of sterility). A user (in some embodiments, the non-sterile nurse, doctor, technician or other non-sterile individual) may break or remove the seal 100 and remove or reposition the cover

16 to allow access to sterile vessel 12. The seal 100 may be any desired mechanism, structure, device or item for sealing cover 16 onto device 10, including frangible tabs, adhesive tape, gaskets, tamper indicating mechanisms, or any other suitable structure or mechanism for sealing cover 16 prior to removal or repositioning. Fig. 1 shows seal 100 as an adhesive tape at least partially encircling the connection between cover 16 and the rest of housing 14. In still other embodiments, a separate mechanism, structure, device or item is not necessary to seal cover 16 to the rest of housing 14 and the cover is formed integrally with the rest of housing 14. In such embodiments, cover 16 may be punctured, broken or otherwise destroyed once it is desired to access sterile vessel 12. In other embodiments, a seal is unnecessary.

In yet other embodiments, cover 16 is unnecessary. For example, the housing 14 may include an aperture in which sterile vessel 12 is located. Sterile vessel 12 may be positioned deep enough within the housing 14 such that non-sterile persons or things cannot easily contact sterile vessel 12. In such embodiments, device 10 may include a slider or other mechanism for facilitating access to the sterile vessel 12 at the appropriate time. For example, in some embodiments, actuation of the slider may raise sterile vessel 12 into an accessible position. In other embodiments, as the sterile vessel 12 fills with material (described further below), a plunger of the vessel may extend outside of the housing, allowing a sterile nurse, doctor or technician to grasp the end of the plunger and remove sterile vessel 12 from device 10. In some embodiments, the housing 14 may include a plastic film over the aperture or other portions of the housing 14, such that breaking the film allows access to the vessel 12.

The device 10 of Fig. 1 also includes a material input 18. As discussed above, material may be any material that a user desires to transfer into a sterile vessel 12, including blood, blood components (such as platelets or blood plasma), bone cement, ceramics, allogenic bone, autologous bone, bone marrow, other fluids, or any other material. Material input 18 may be configured to receive and convey any desired material into device 10. In one embodiment, material input 18 includes an aperture that corresponds to the size and shape of a syringe tip such that material input 18 receives the tip in a manner that substantially

prevents leakage. In some embodiments, material input 18 is an aperture in housing 14 that allows the syringe or other vessel to interact with internal components such that the syringe can introduce material into device 10. Material input 18 may also include a gasket or other appropriate structures or mechanisms for lessening the chance of leakage. In other embodiments, material input 18 does not interact with a syringe to receive material, but is sized, shaped and positioned for material to be poured directly into material input 18. For example, in some embodiments, material input 18 may be a funnel.

In still other embodiments, material input 18 may comprise other structures or mechanisms for facilitating the input of material into device 10. Additionally, material input 18 may or may not include a check valve or other appropriate structures and mechanisms for preventing material from flowing back out of material input. In some embodiments, material input 18 may include a filter, such as a screen, or other structure for separating impurities or other things from material during input into device 10.

The device 10 shown in Fig. 1 also includes an actuator 20. The actuator 20 may be a slide (such as shown in Figs. 1 and 5(a)), a knob, a button (such as shown in Figs. 6(a), 7(a), 8(a) and 9(a)) or other suitable structure or mechanism for commencing processes or otherwise affecting structures inside device 10, some examples of which are discussed further below. Although Fig. 1 shows device 10 as only including a single actuator 20, devices 10 in accordance with embodiments of this invention may include any number of actuators 20 for controlling or affecting various internal components of device 10. In still other embodiments, an actuator 20 is unnecessary.

The device 10 of Fig. 1 also includes a window 22. In some embodiments, window 22 may be a transparent or semi-transparent window. Window 22 may allow viewing of one or more of the internal components of device 10 and/or the progress of the inputted material through the same. As shown in Figs. 1, 5(a), 6(a), 7(a), 8(a) and 9(a), the size, shape, number and position of windows 22 may be varied to facilitate viewing various interior portions and/or components of device 10. In other embodiments, window 22 is unnecessary and/or other features of device 10 indicate the progress of the inputted material through

device 10. For example, sterile vessel 12 may include a plunger that extends as material fills the vessel 12, which may roughly indicate the amount of material that has moved into the vessel. In some embodiments, device 10 does not include any features or components for indicating the progress of material through device 10.

In the configuration shown in Fig. 1, device 10 includes a second material input 24. Like embodiments of material input 18 described above, second material input 24 may interact with the tip of a syringe 54 (shown in Figs. 2 – 4) to receive and convey a material into device 10 or may include other structures and mechanisms as discussed above for material input 18. Second material input 24 is also discussed further below.

In the configuration shown in Fig. 1, device 10 also includes a base 26. Base 26 may maintain the device 10 in an upright orientation when placed on a surface. Moreover, if desired, a user may push down on base 26 to stabilize device 10 during use. As shown in Figs. 5(a) – 9(b), base 26 may be formed in a wide variety of shapes, sizes and configurations.

The devices 10 shown in Figs. 1 – 9(b) are configured to separate the platelet component of a blood material and transfer those platelets into sterile vessel 12. Devices 10 in accordance with other embodiments of the present invention, however, may be configured to perform a wide variety of processes on a wide variety of materials. Exemplary processes include, but are not limited to, filtering, mixing, separating, reacting, fabrication, or sterilization. In still other embodiments, device 10 does not process the inputted material at all, but merely transfers the material into sterile vessel 12. Exemplary materials useable in conjunction with devices 10 in accordance with the present invention are discussed above.

Figs. 2 - 4 illustrate various configurations of internal components of device 10 for filtering and transferring the blood platelet component of an inputted blood material into sterile vessel 12. As shown in Figs. 2 - 4, the locations and orientations of the internal components can be varied based on the shape and size of housing 14 (e.g., the configuration of Fig. 2 may be suitable for the housings 14 of Figs. 5(a), 5(b), 7(a), 7(b), 8(a) and 8(b), the configuration of Fig.

3 may be suitable for the housing 14 of Figs. 6(a), 6(b) and 6(c), and the configuration of Fig. 4 may be suitable for the housing 14 of Figs. 9(a) and 9(b)). In the configurations shown in Figs. 2 - 4, device 10 includes the following internal components: material reservoir 28, conduits 30, filter 32, waste reservoir 34, and various valves 36, 38, 40, 42, 44 and 46. Device 10 configurations in accordance with other embodiments of the present invention may exclude some or all of these components and/or include other components.

In the configurations of Figs. 2 - 4, introduction of blood material into device 10 via material input 18 (as discussed above) directs the material into material reservoir 28. Syringe 48 interacts with material input 18 to facilitate the introduction of blood material into device 10 in the embodiments of Figs. 2 - 4, however, other vessels, devices or methods can also be used to introduce a material into devices 10 in accordance with the present invention (some examples of which, but not all, are discussed above). In the configurations of Figs. 2 - 4, depressing a plunger 50 associated with the syringe 48 may increase the pressure on blood material within syringe 48, causing it to flow through material input 18 into material reservoir 28.

Figs. 2 - 4 show a conduit 30 for directing material from syringe 48 into material reservoir 28. Other portions of conduit 30 shown in Figs. 2 - 4 direct the movement of materials and components of materials between other components of device 10. In the embodiments shown in Figs. 2 - 4, conduit 30 is a plastic tubing, although in other embodiments, conduit 30 may be any suitable device, structure or mechanism for containing and/or facilitating the movement of material between various components of device 10. In some embodiments, integral portions of material input 18 are a conduit for directing material into material reservoir 28 or other components of device 10.

The devices 10 of Figs. 2 - 4 include a check valve 36 positioned where material is input into material reservoir 28. Check valve 36 may regulate the flow of material such that material can enter material reservoir 28 through check valve 36, but may not exit material reservoir 28 through check valve 36. Check valve 36 may prevent leakage of material from device 10 once the material has entered material reservoir 28. In other embodiments, check valve 36 is unnecessary. For