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(54) **SYSTEMS AND METHODS FOR INJECTION  
AND ASPIRATION**

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(2) Date: **Mar. 7, 2025**

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(60) Provisional application No. 63/579,255, filed on Aug. 28, 2023.

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(51) **Int. Cl.**

**A61M 3/02** (2006.01)

**A61M 1/00** (2006.01)

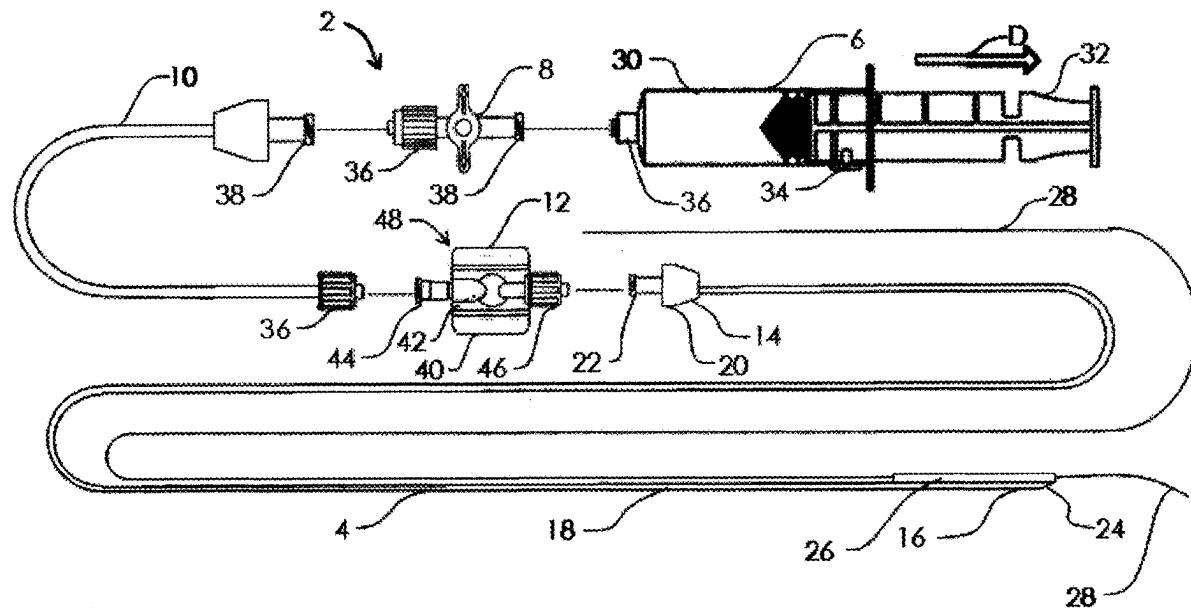
(52) **U.S. CL.**

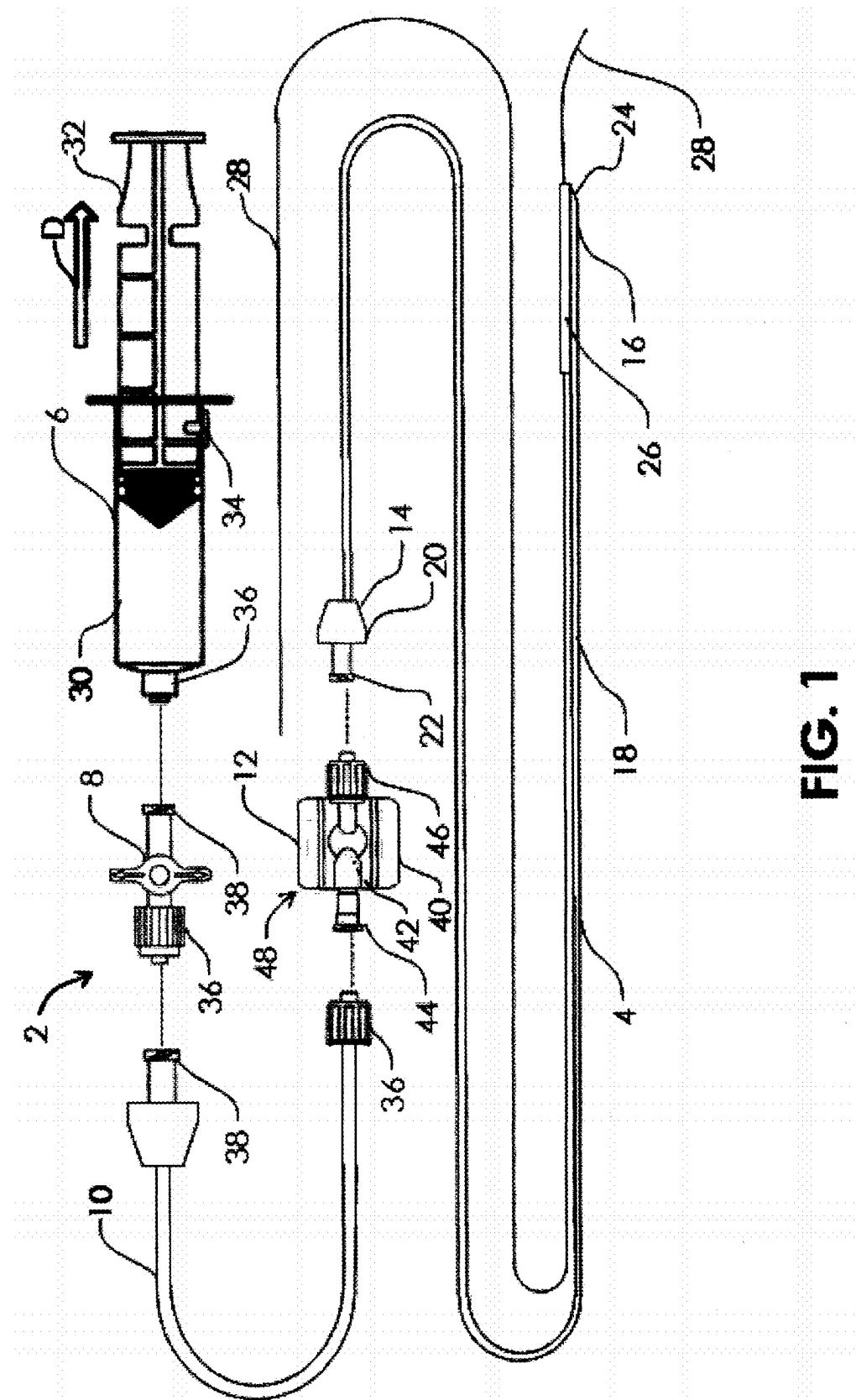
CPC ..... **A61M 3/0283** (2013.01); **A61M 3/0275** (2013.01); **A61M 1/77** (2021.05); **A61M 1/79** (2021.05); **A61M 2205/10** (2013.01); **A61M 2205/15** (2013.01); **A61M 2205/18** (2013.01); **A61M 2205/3344** (2013.01); **A61M 2205/581** (2013.01); **A61M 2205/582** (2013.01); **A61M 2205/583** (2013.01); **A61M 2210/12** (2013.01)

(57)

**ABSTRACT**

A system for catheter-based aspiration includes an aspiration catheter having a distal portion configured for insertion within a blood vessel of a subject, the aspiration catheter including an aspiration lumen having a distal opening at the distal portion of the aspiration catheter, an injection lumen having a distal end at the distal portion of the aspiration catheter, and an orifice located at or near the distal end of the injection lumen, the orifice configured to direct liquid into the aspiration lumen at or near the distal opening of the aspiration lumen; an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the aspiration lumen; and a mechanical oscillator coupled to the injector and configured to cause a pulsatile pressure of the liquid as it is injected through the injection lumen.





**FIG. 1**

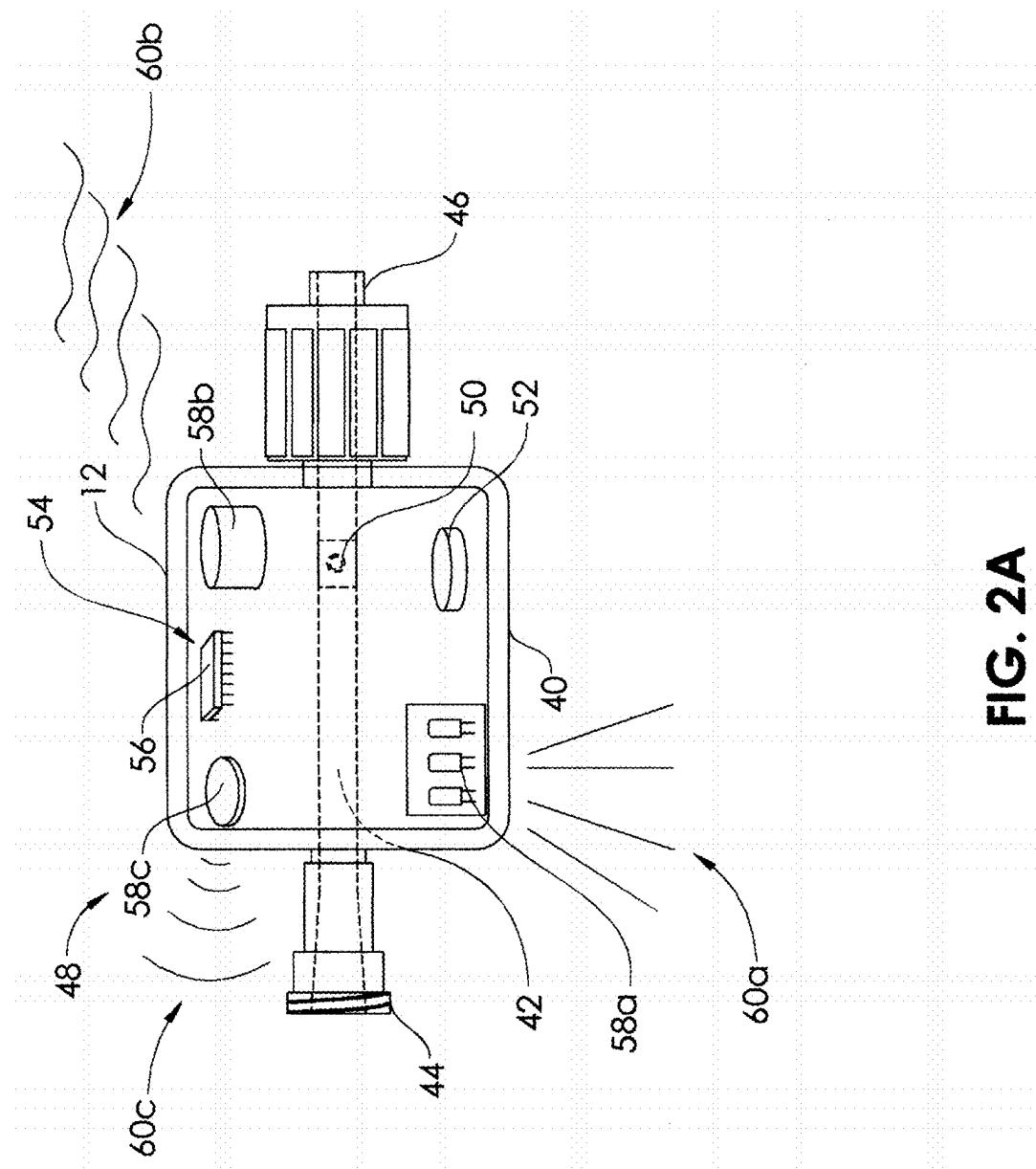
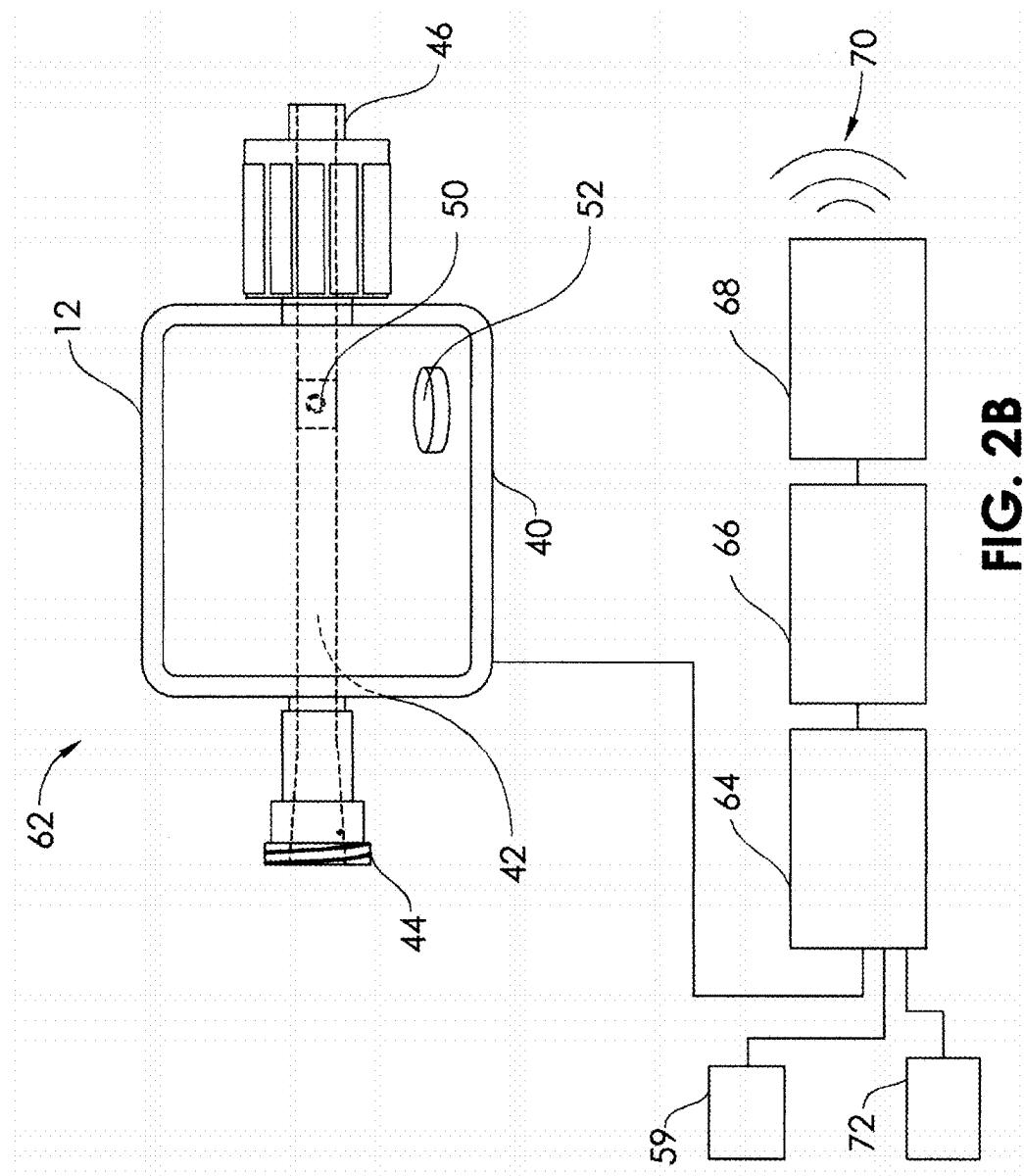
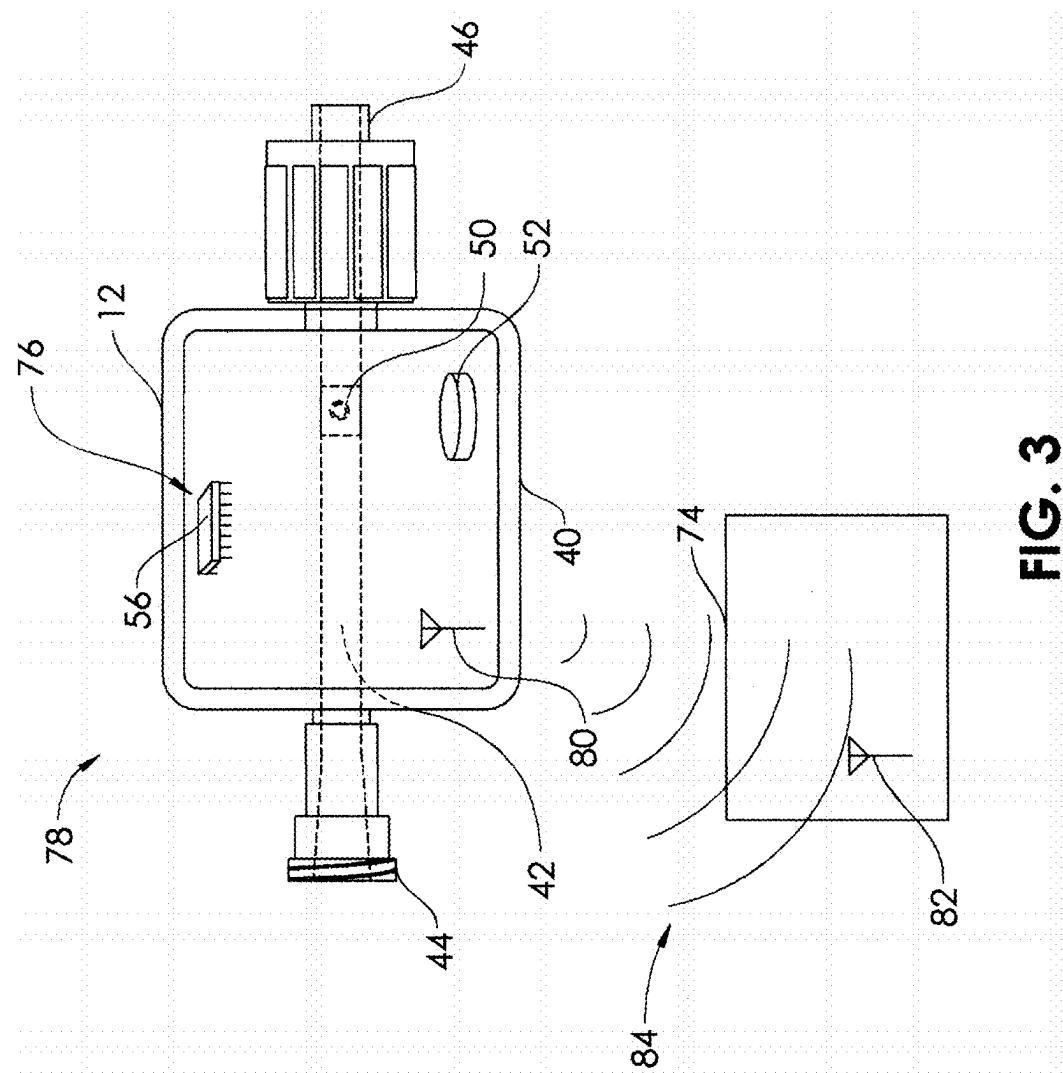
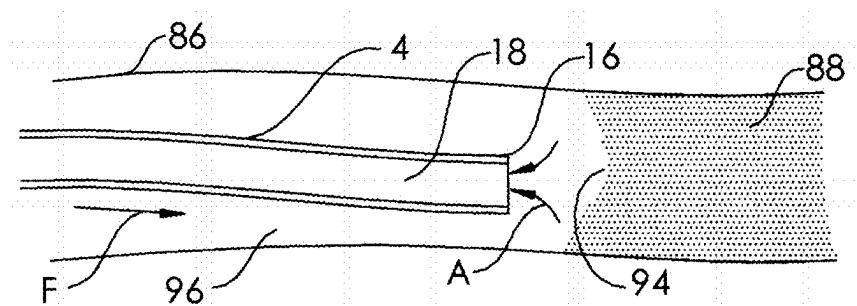


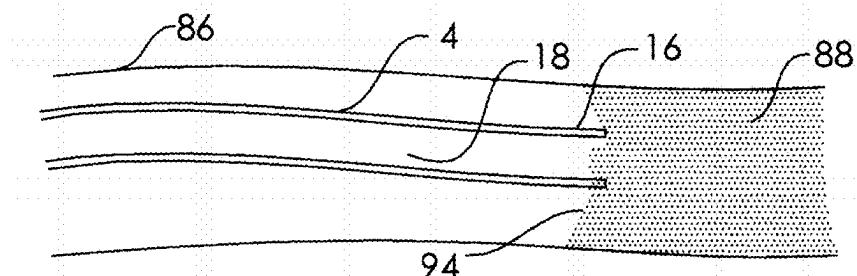
FIG. 2A



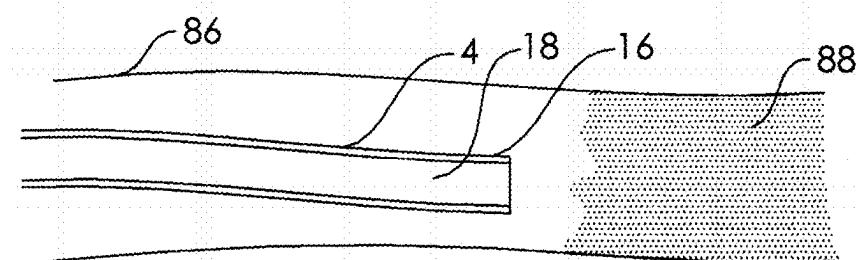




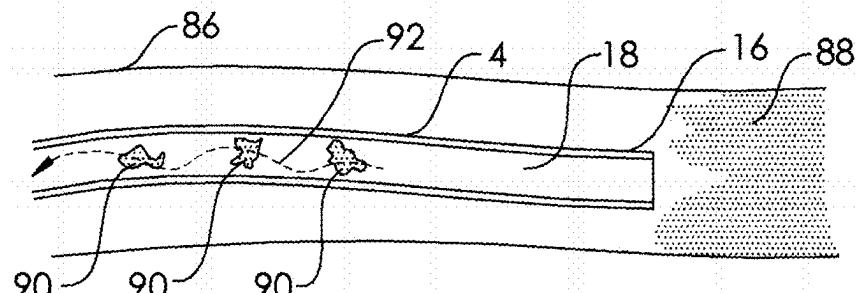
**FIG. 4A**



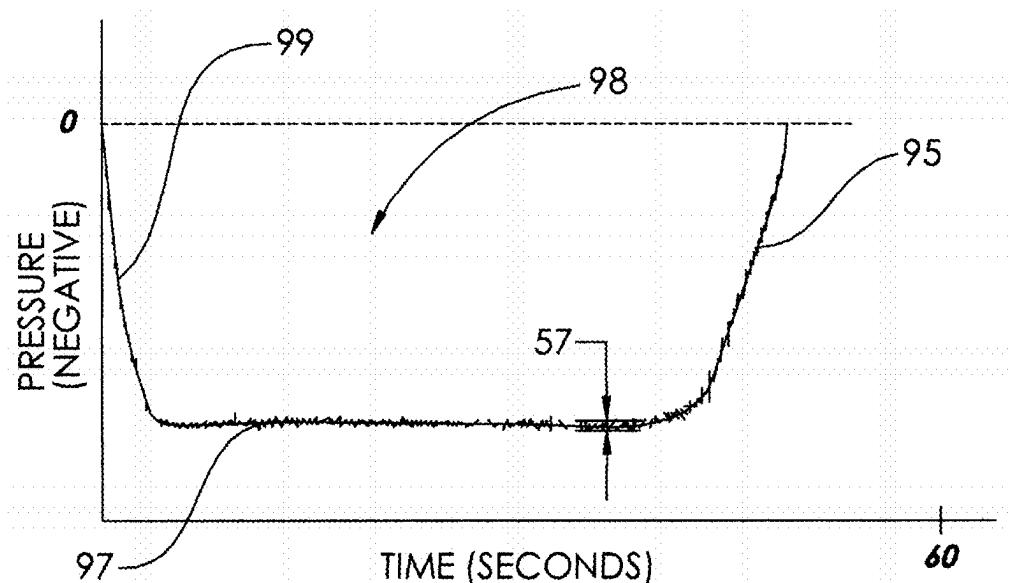
**FIG. 4B**



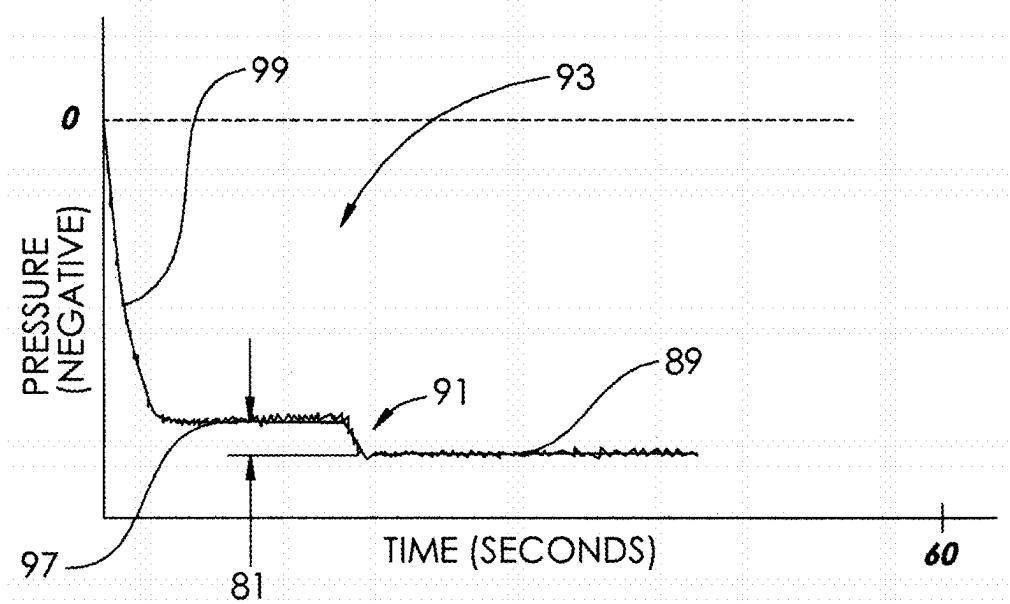
**FIG. 4C**



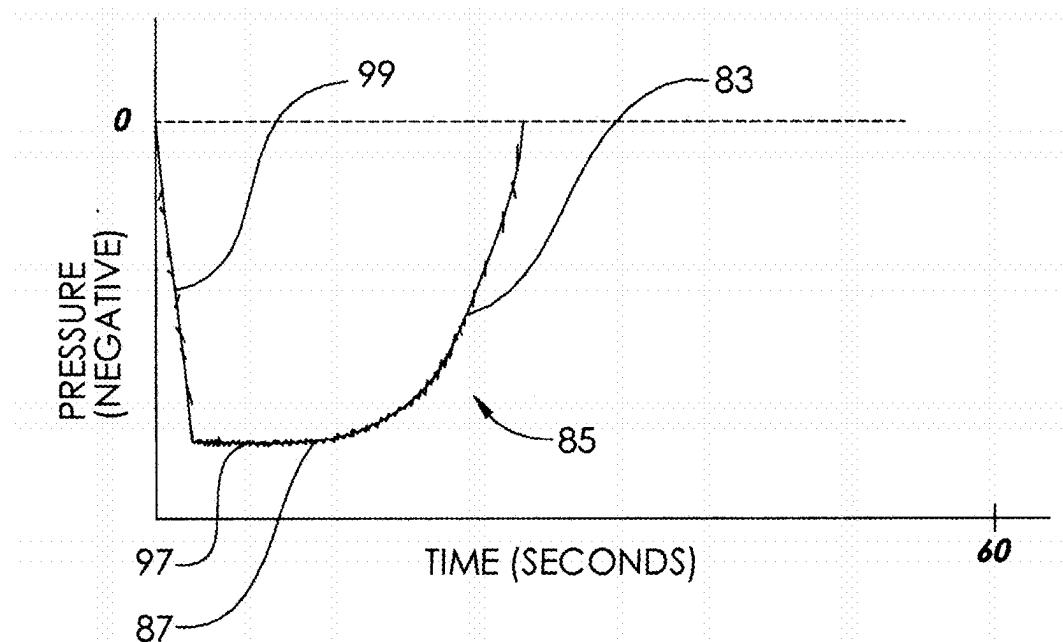
**FIG. 4D**



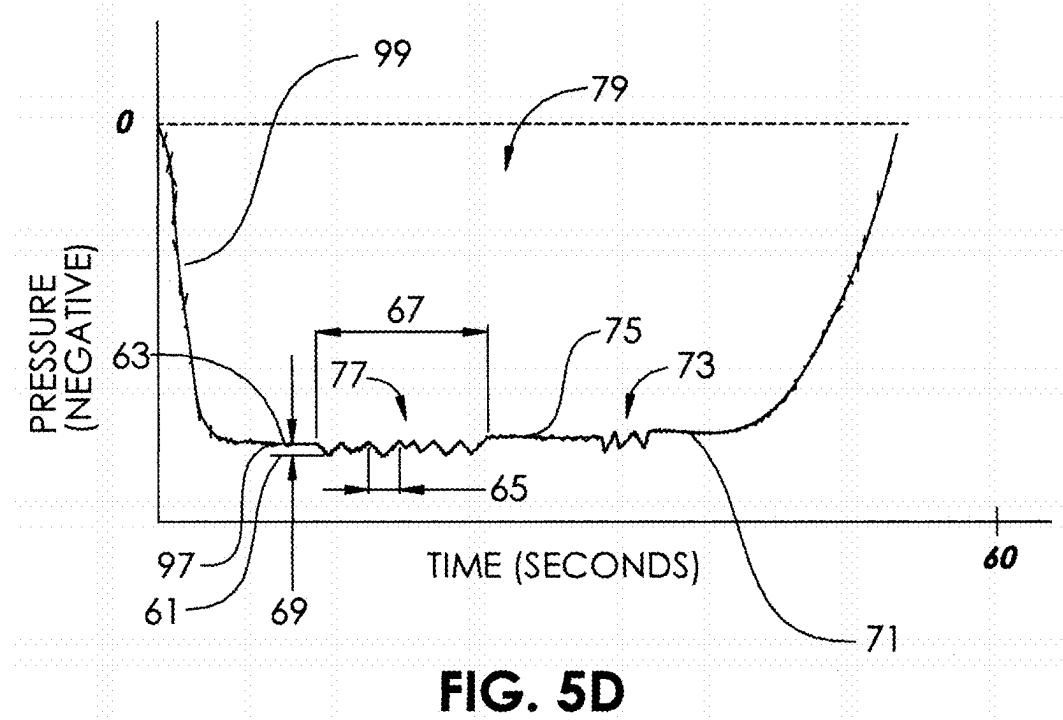
**FIG. 5A**



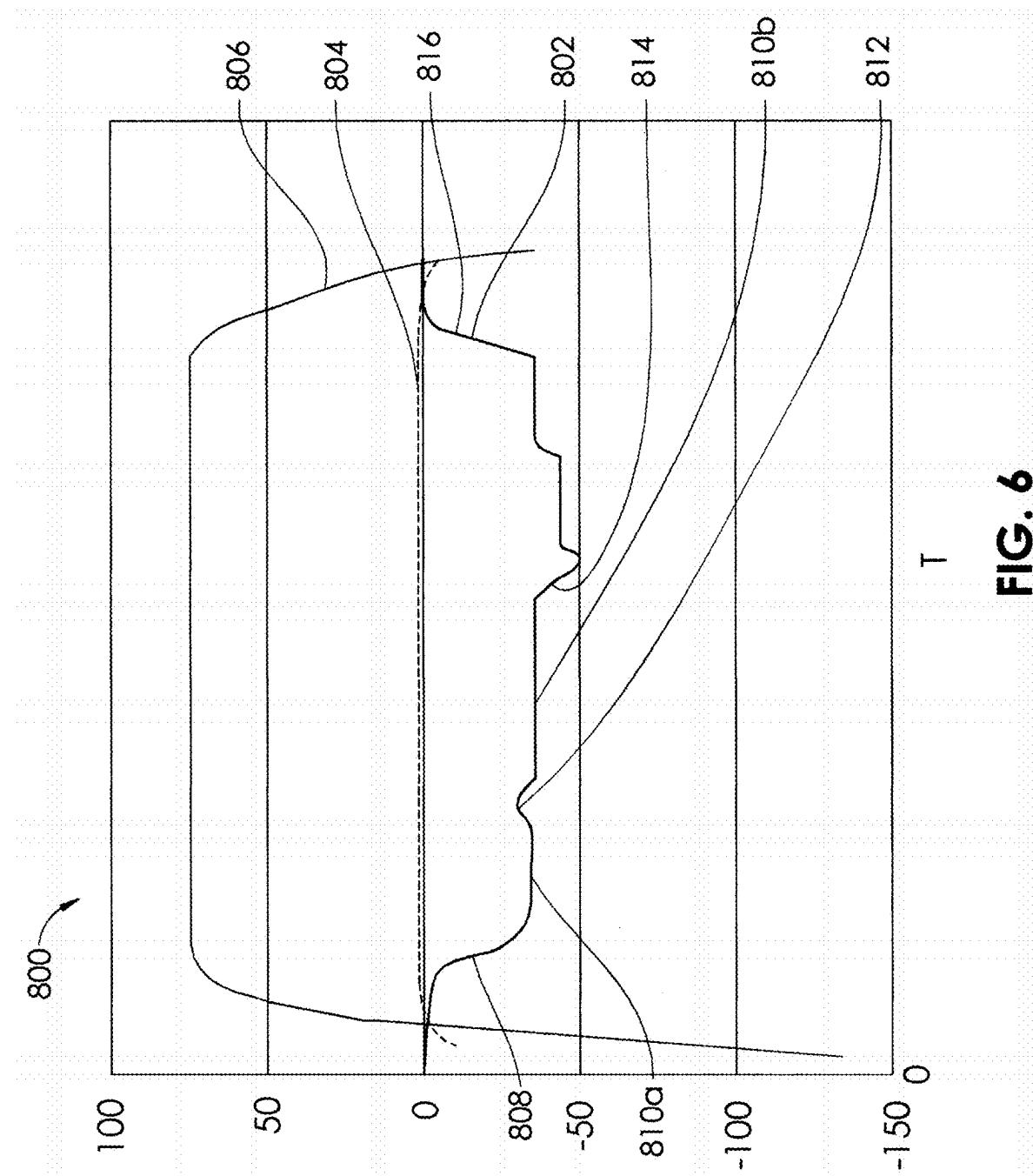
**FIG. 5B**

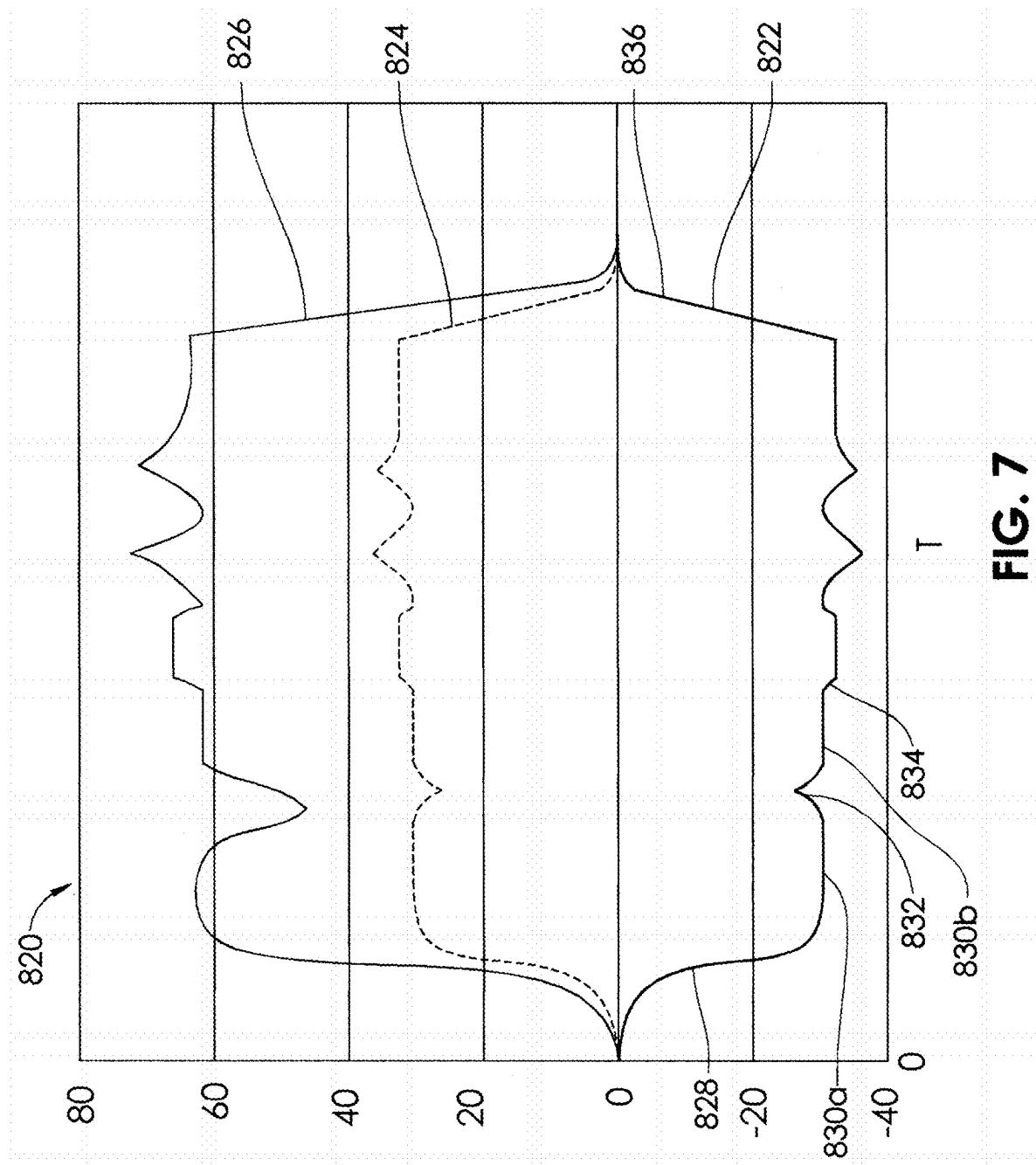


**FIG. 5C**

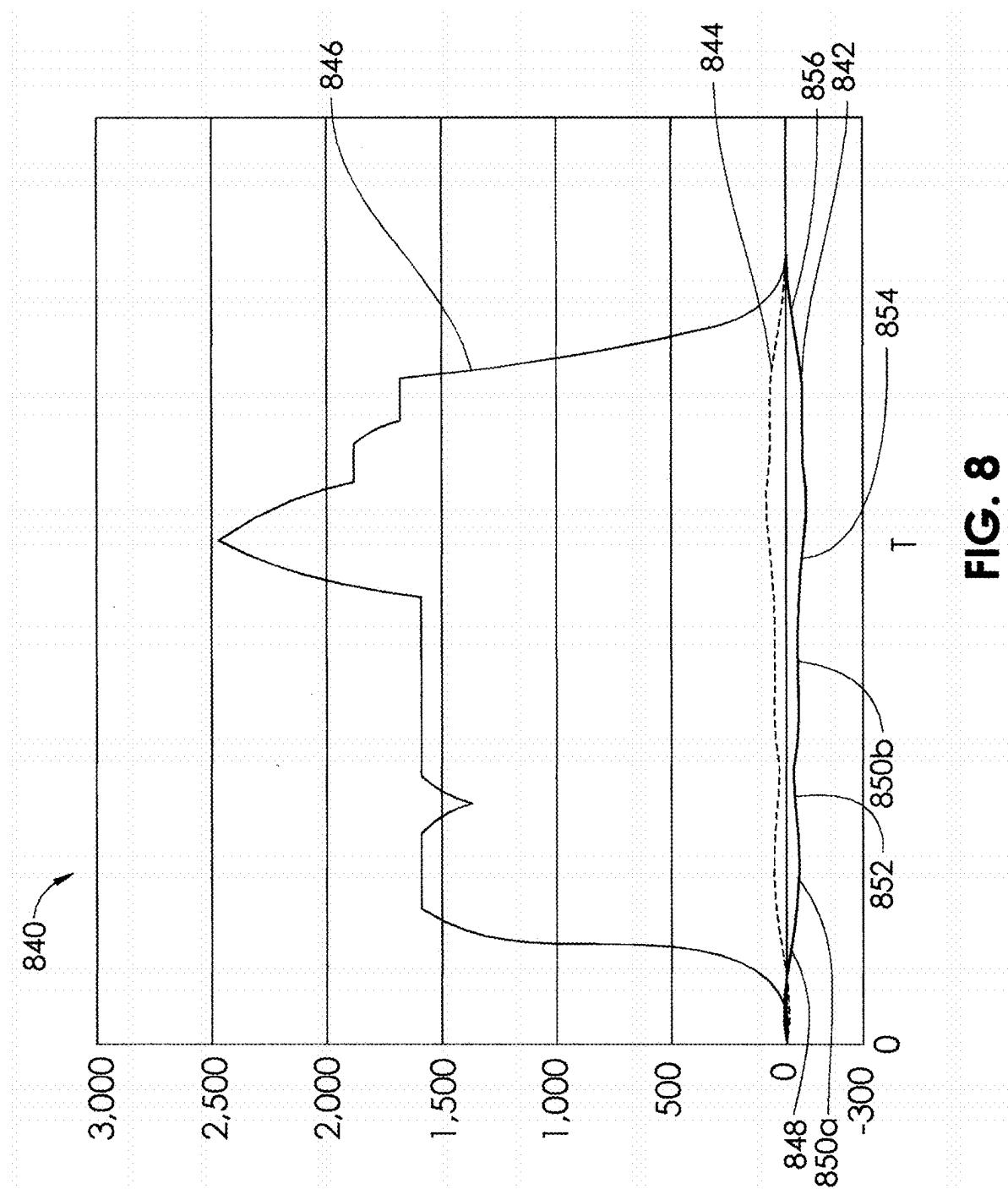


**FIG. 5D**

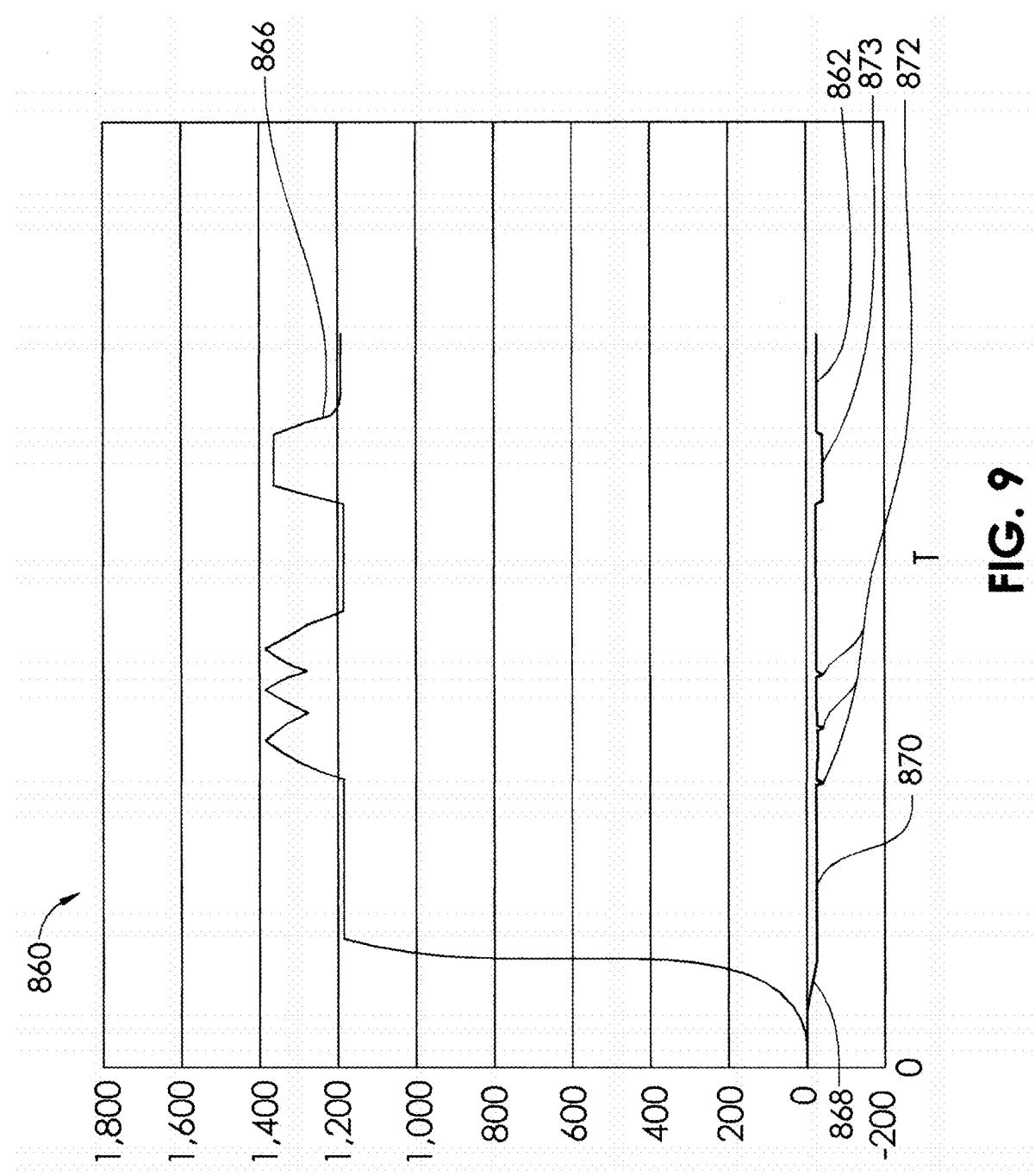




**FIG. 7**



**FIG. 8**



**FIG. 9**

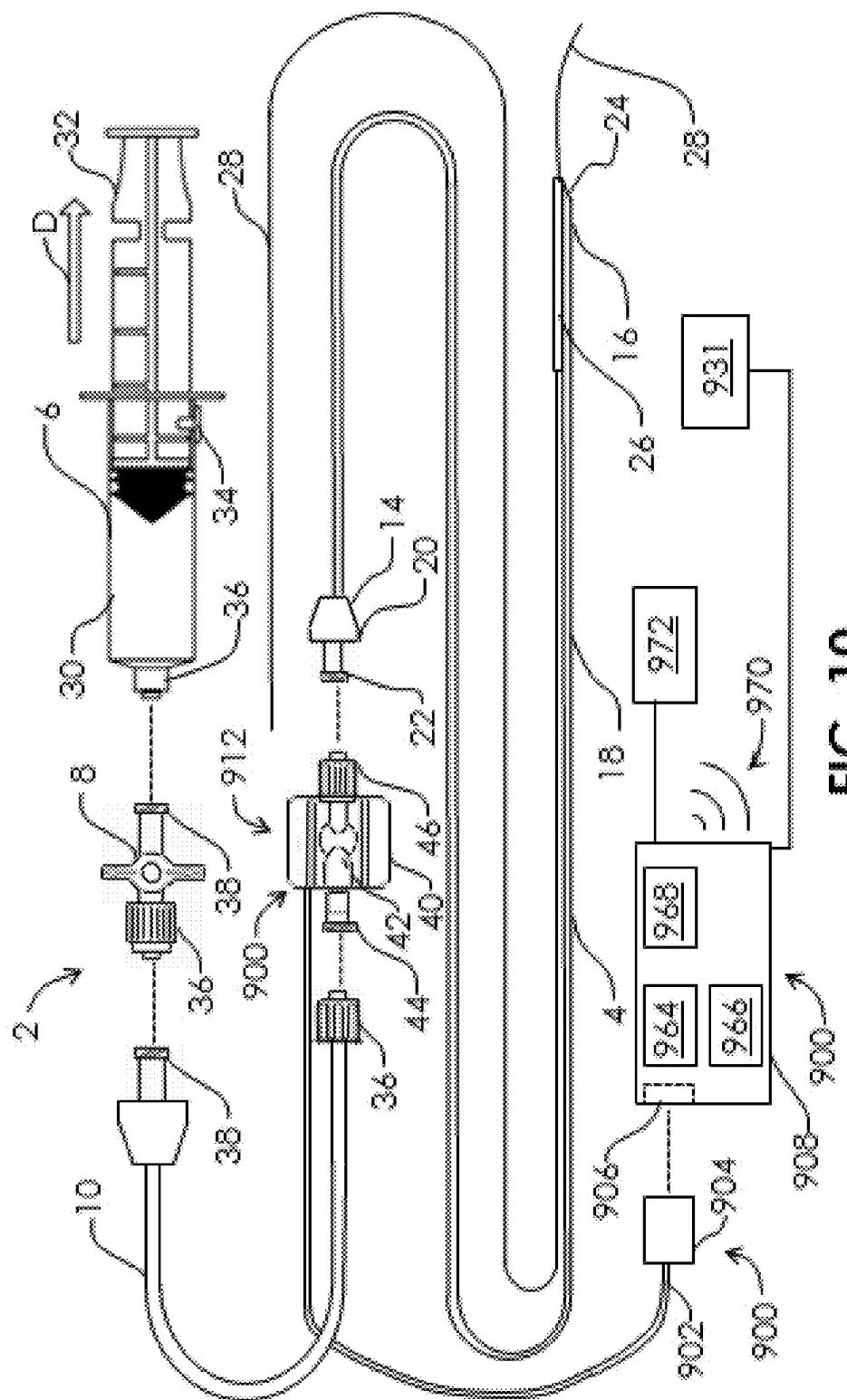


FIG. 10

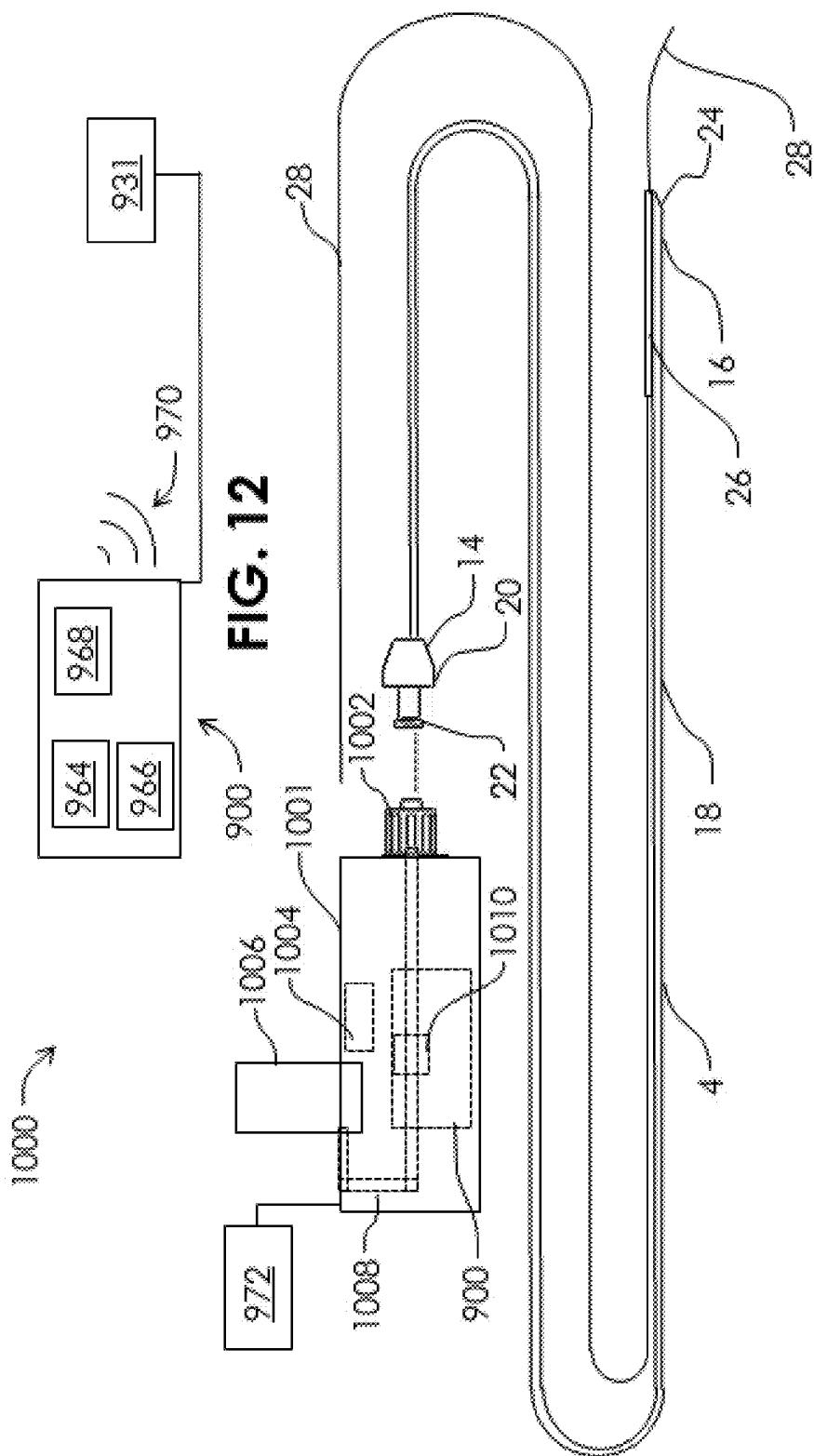
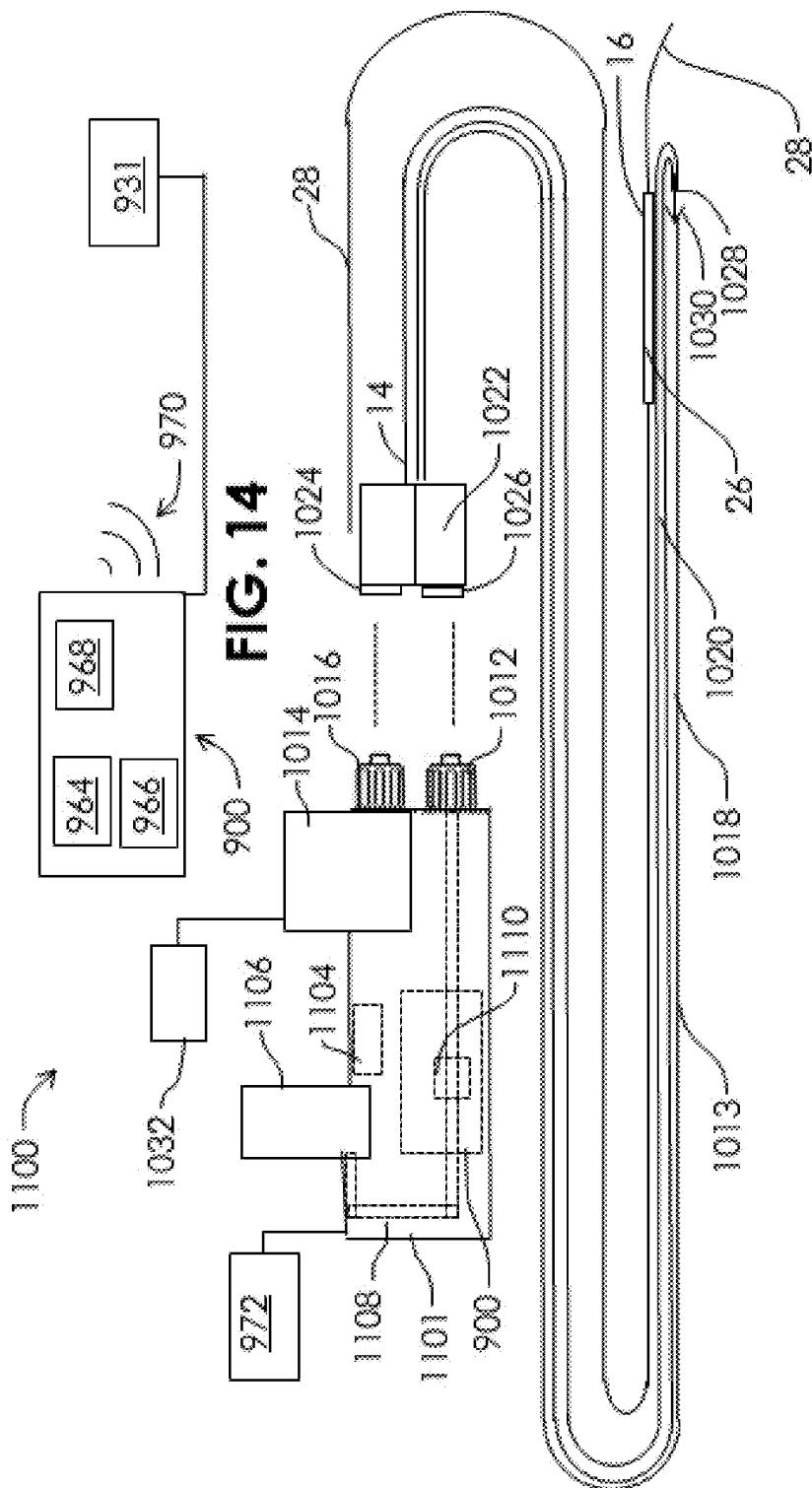
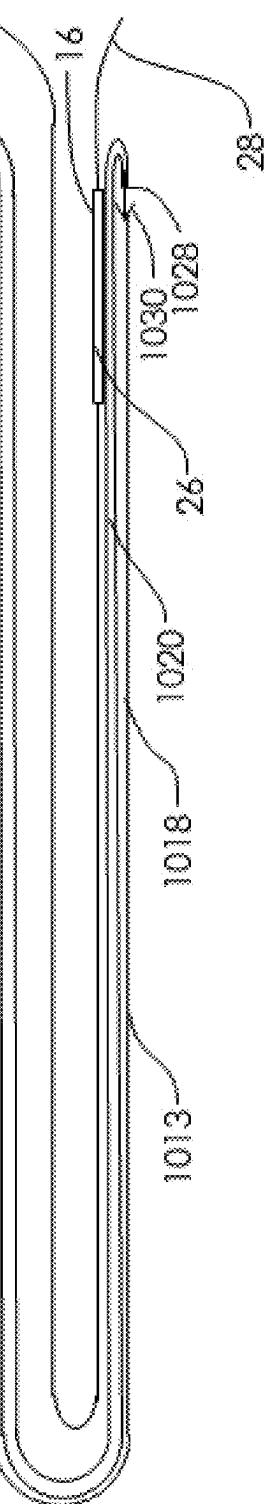


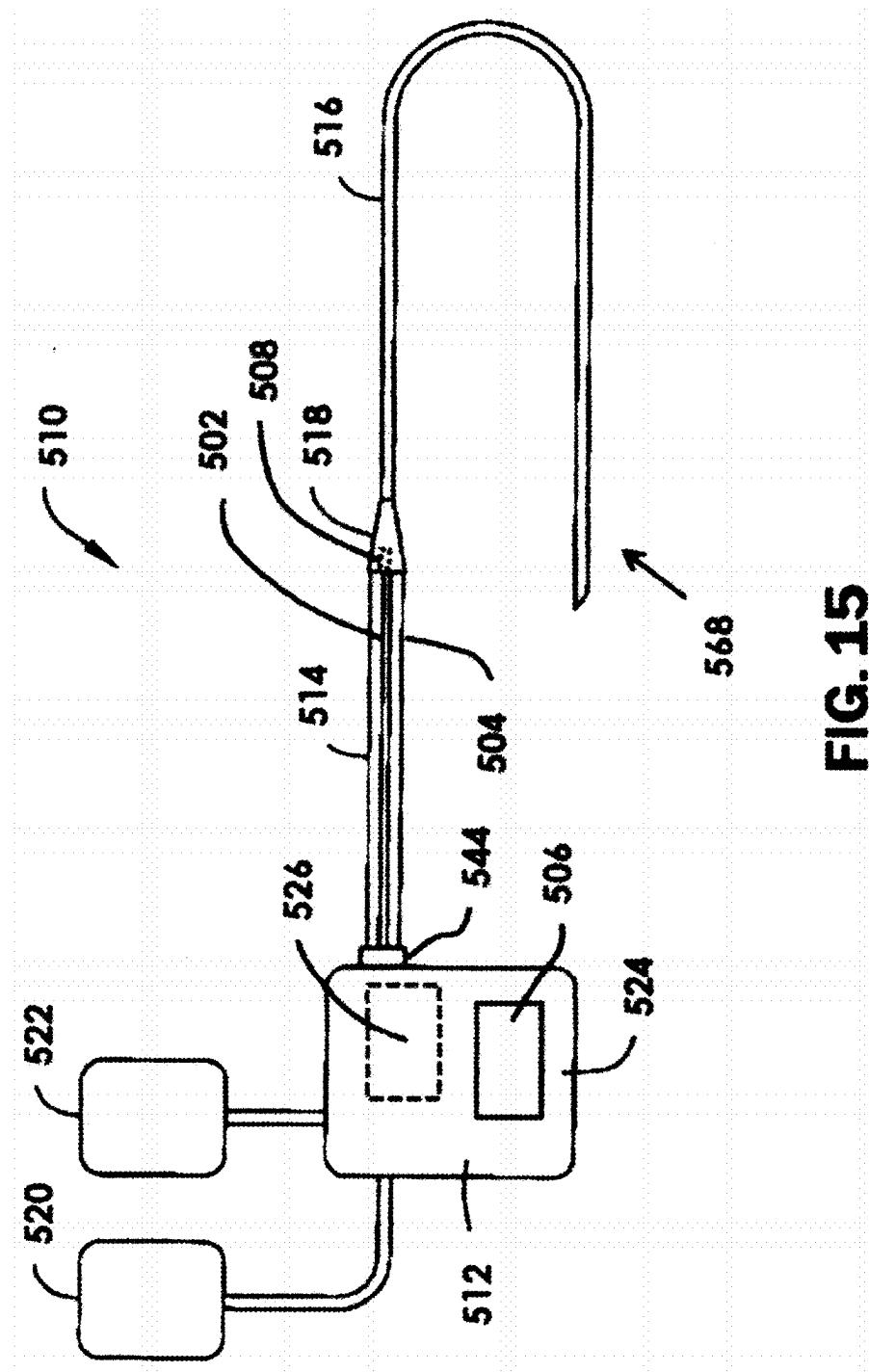
FIG. 11



**FIG. 14**

**FIG. 13**





**FIG. 15**

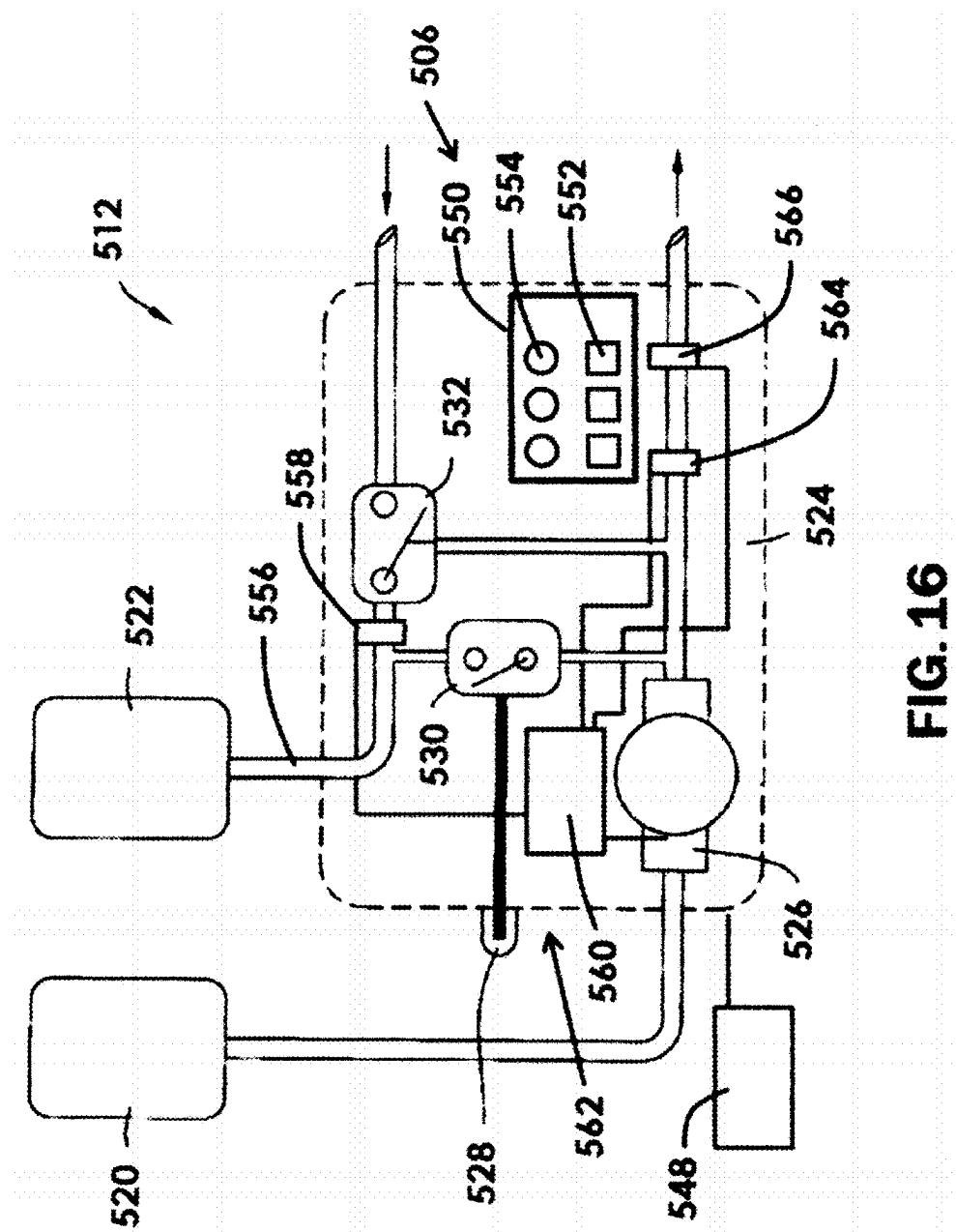
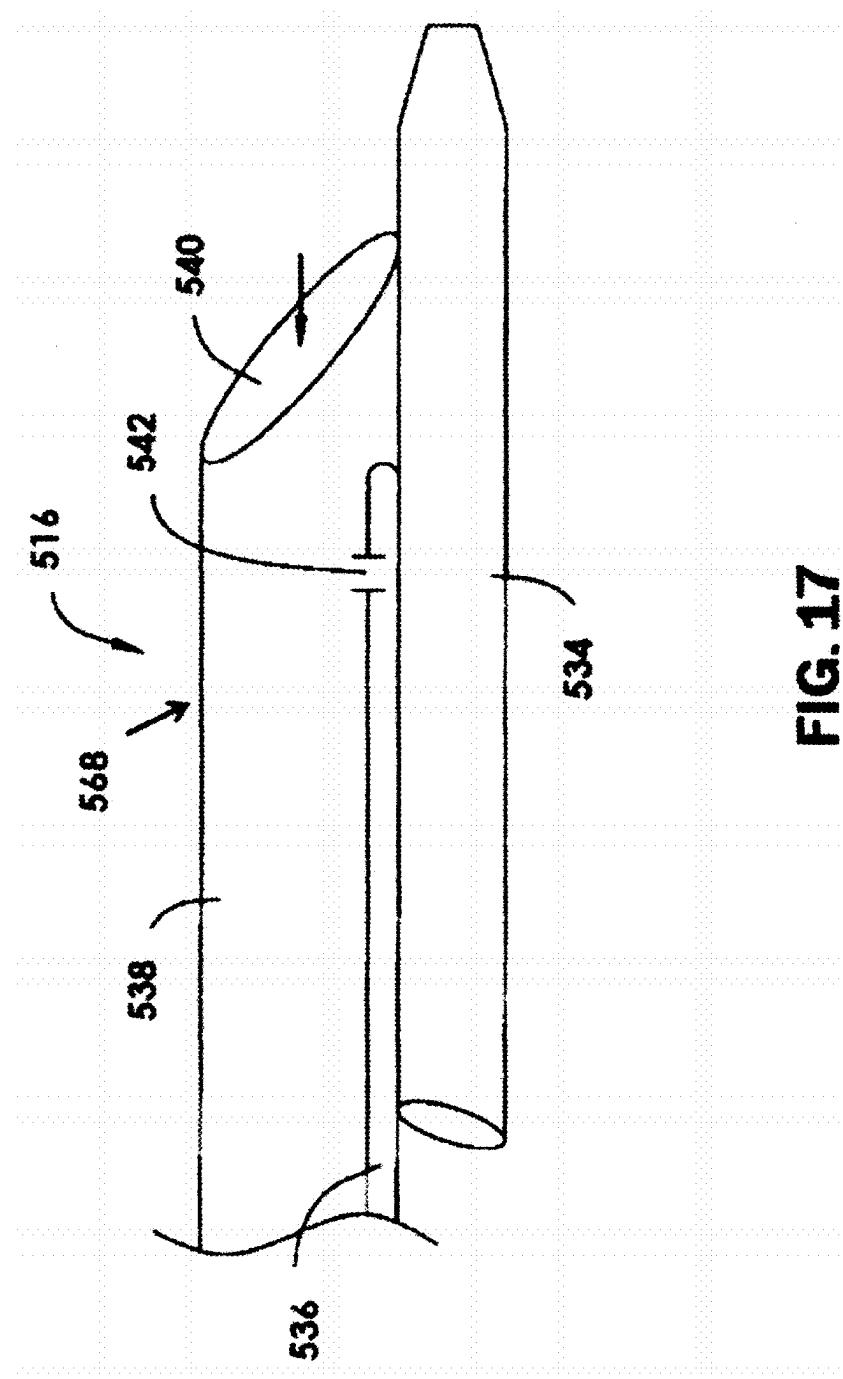
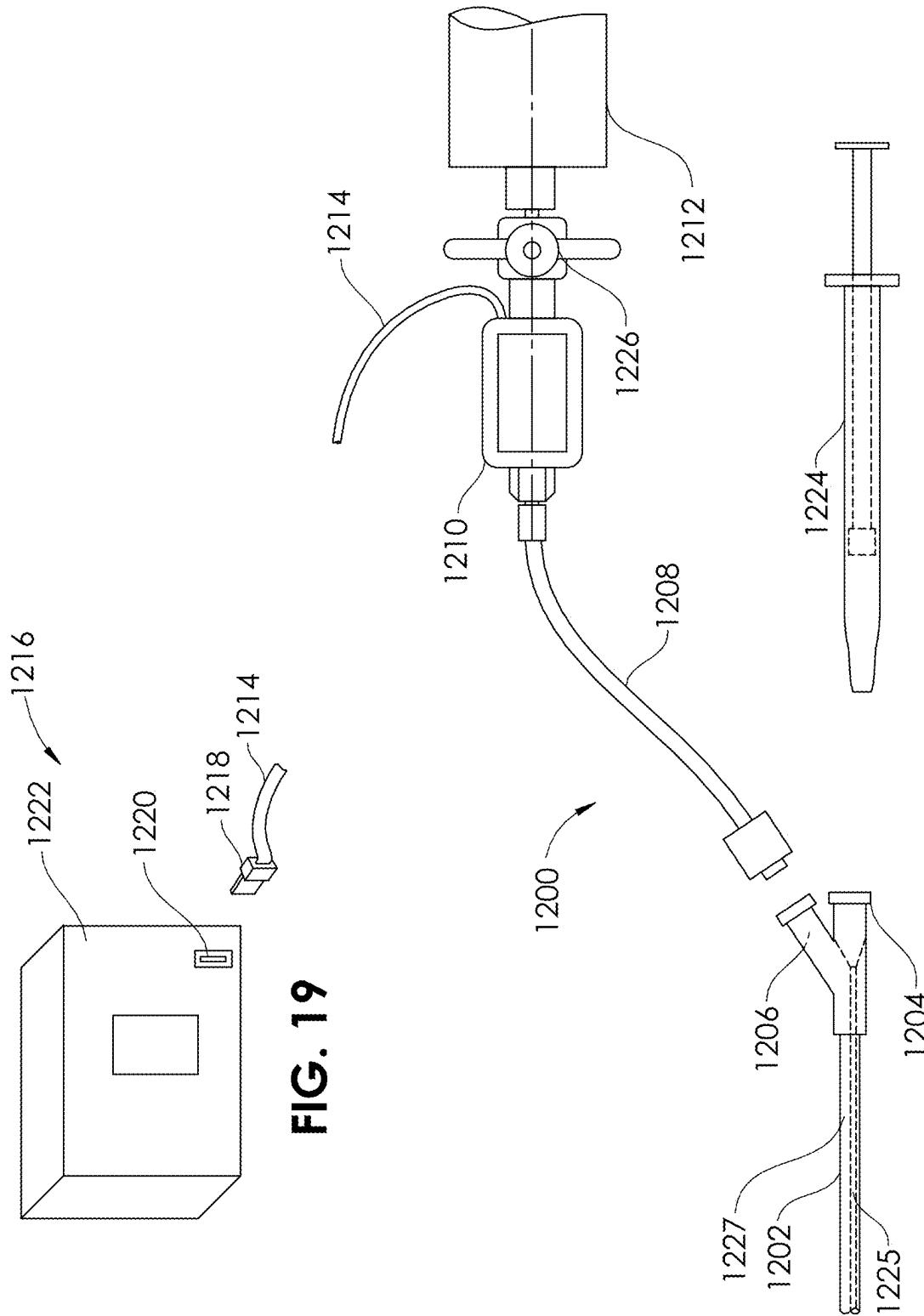


FIG. 16

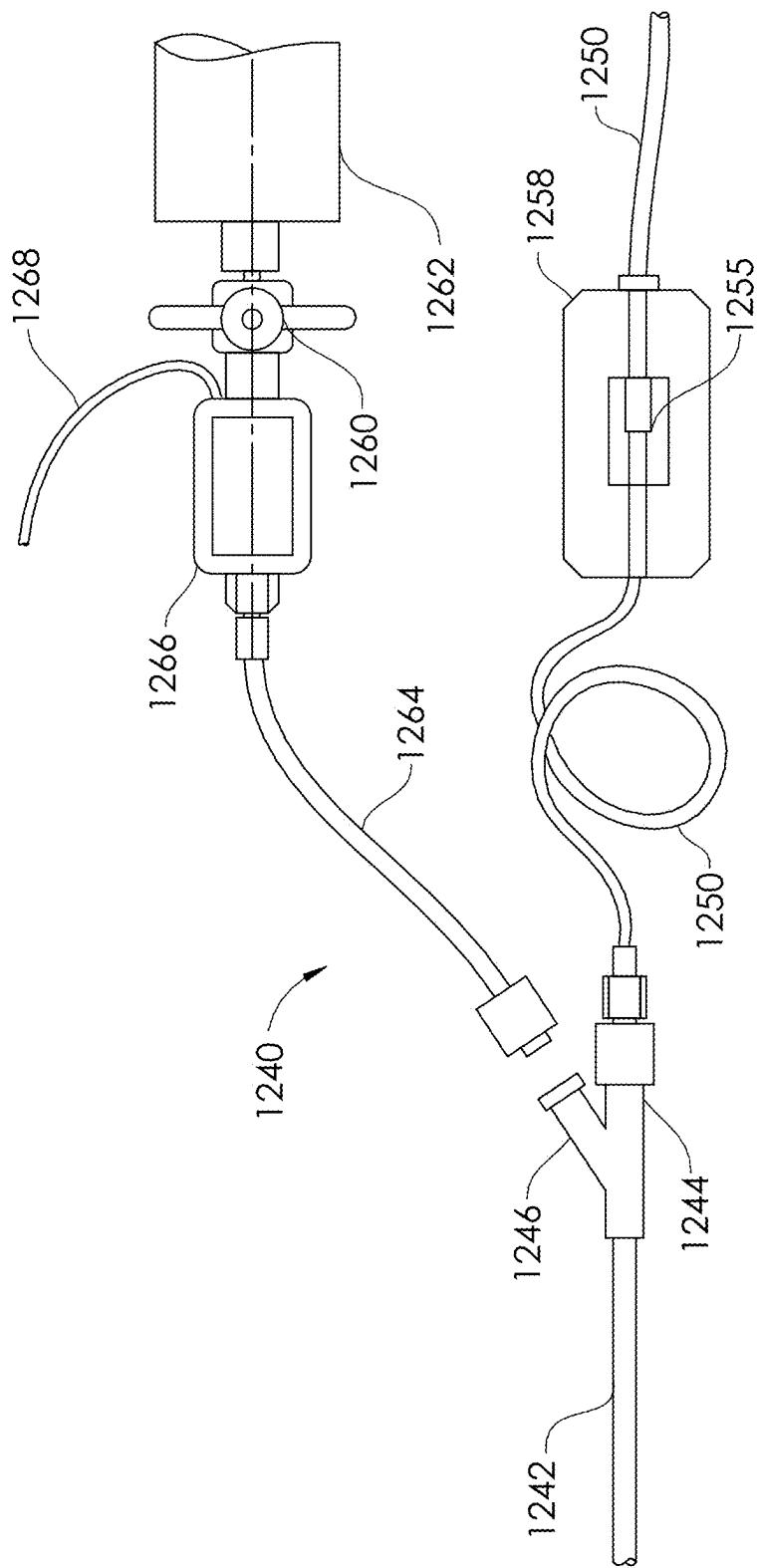


**FIG. 17**

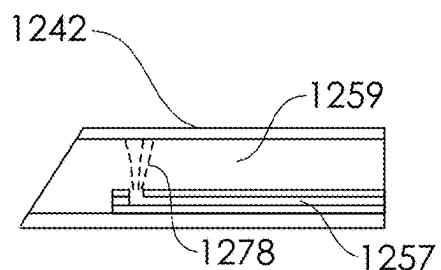


**FIG. 18**

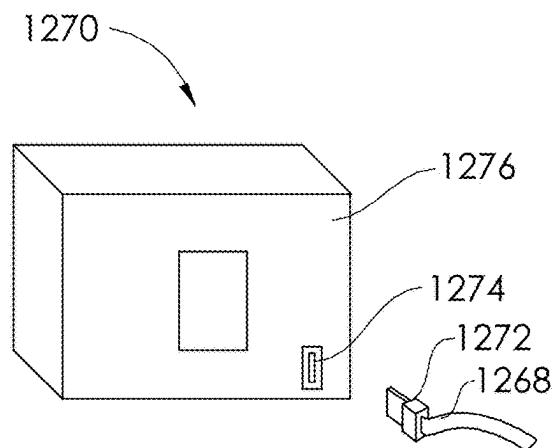
**FIG. 19**



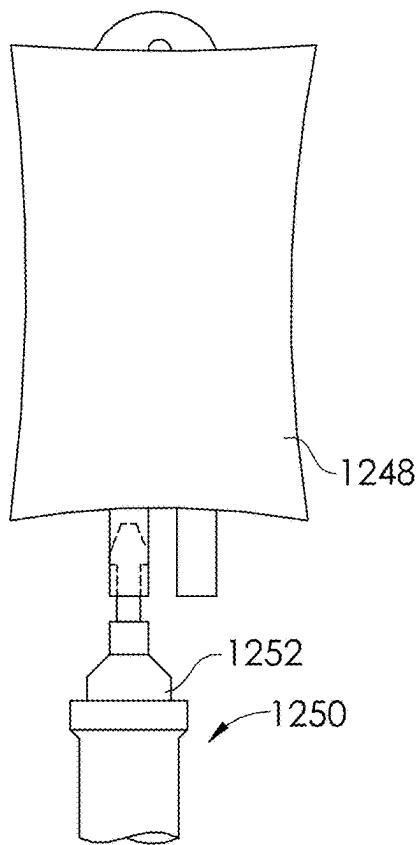
**FIG. 20**



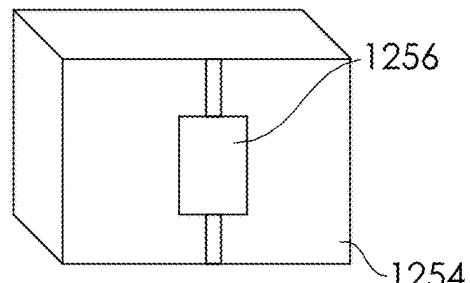
**FIG. 21**



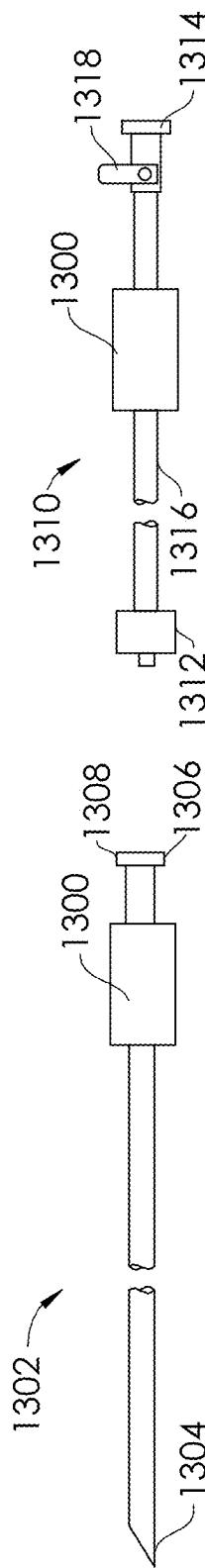
**FIG. 22**



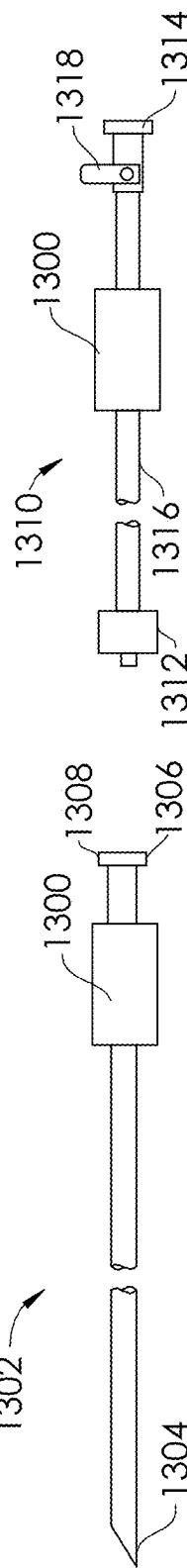
**FIG. 23**



**FIG. 24**



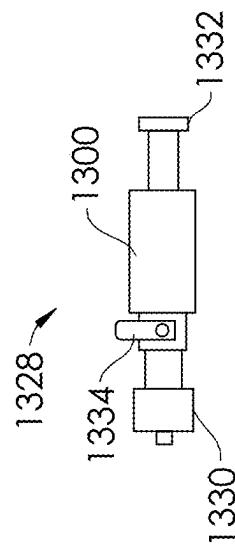
**FIG. 25**



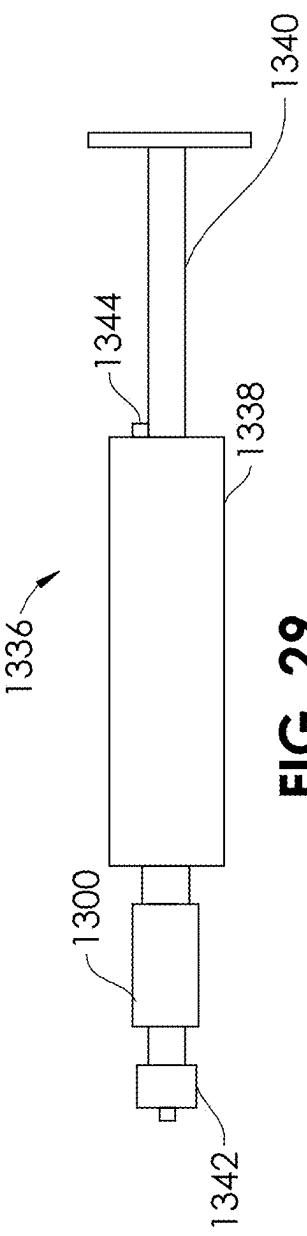
**FIG. 26**



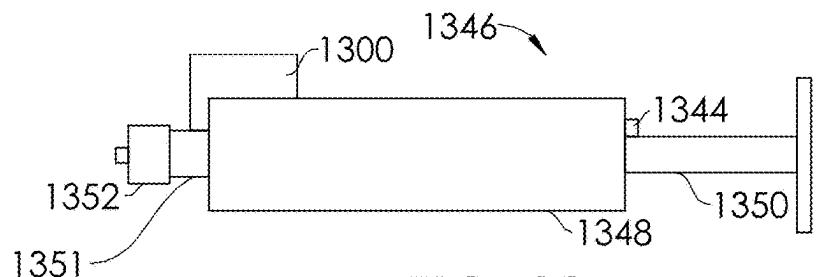
**FIG. 27**



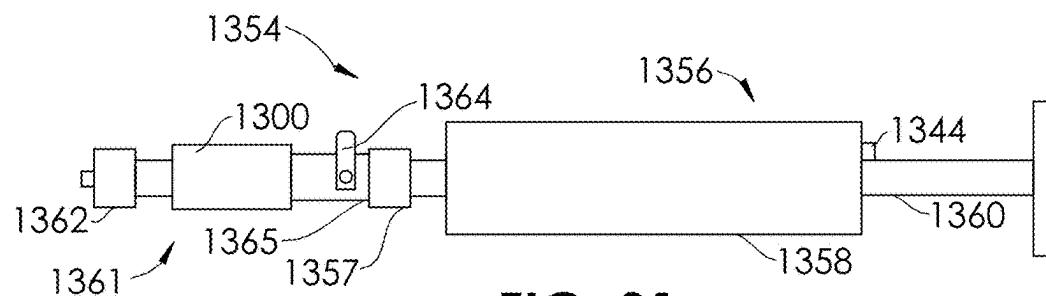
**FIG. 28**



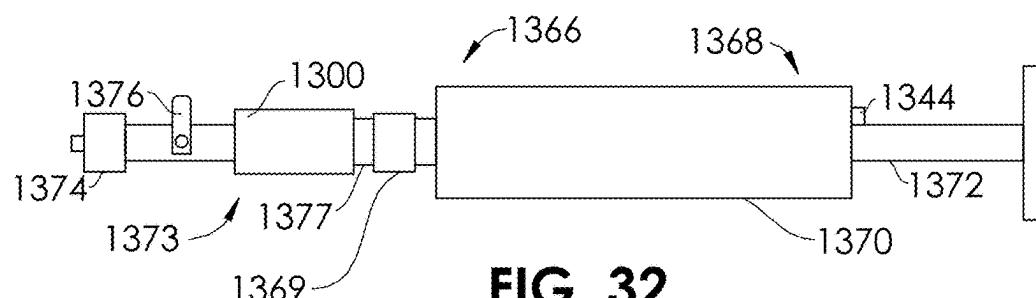
**FIG. 29**



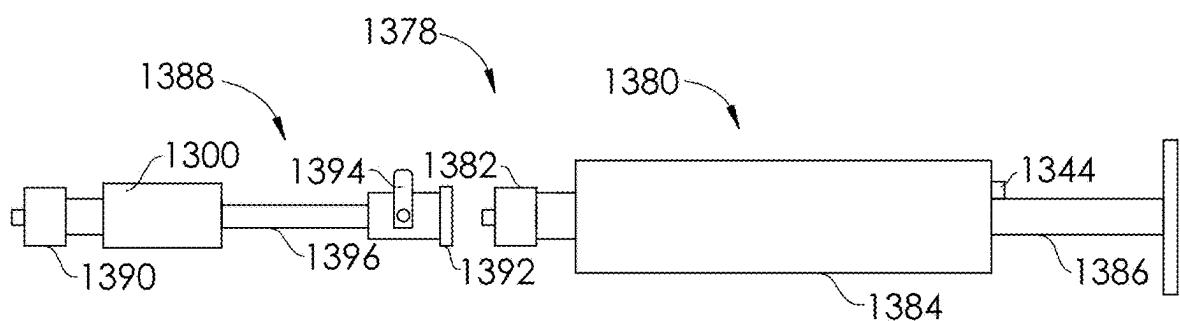
**FIG. 30**



**FIG. 31**



**FIG. 32**



**FIG. 33**

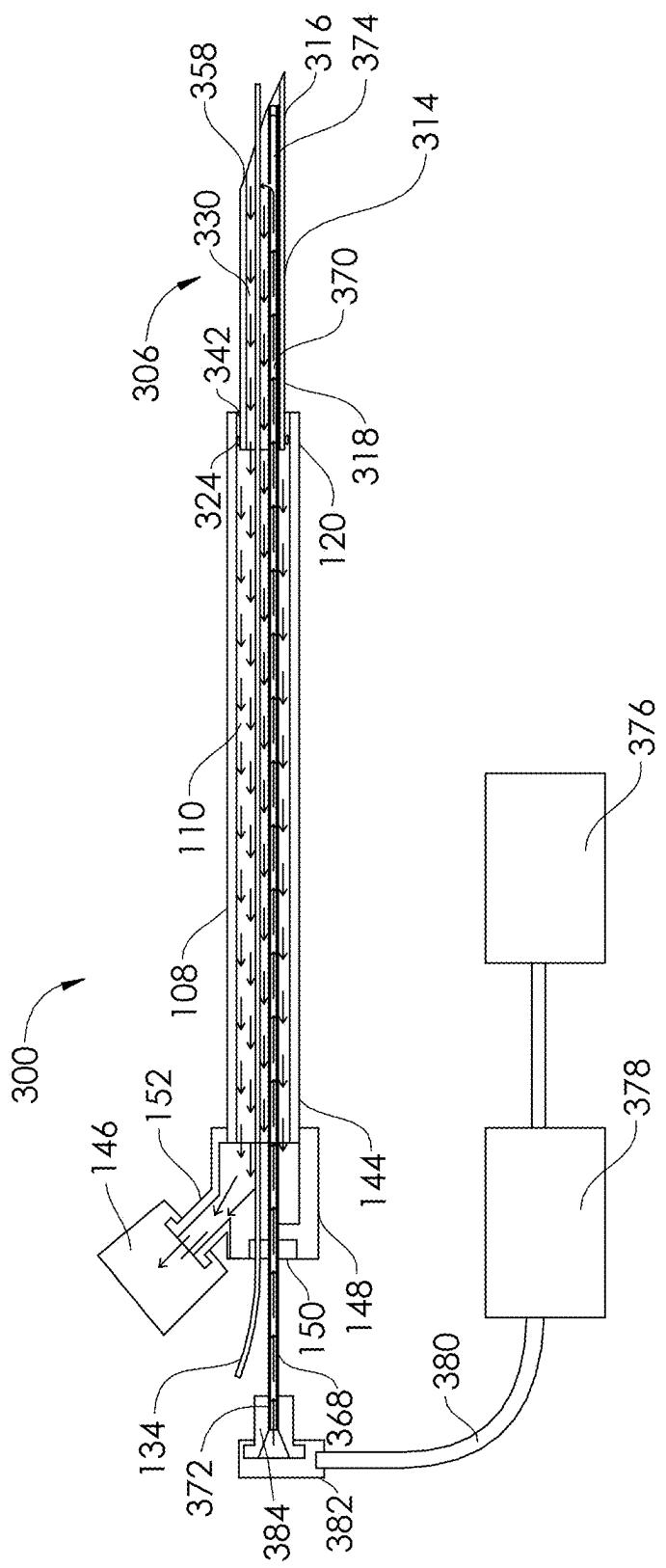
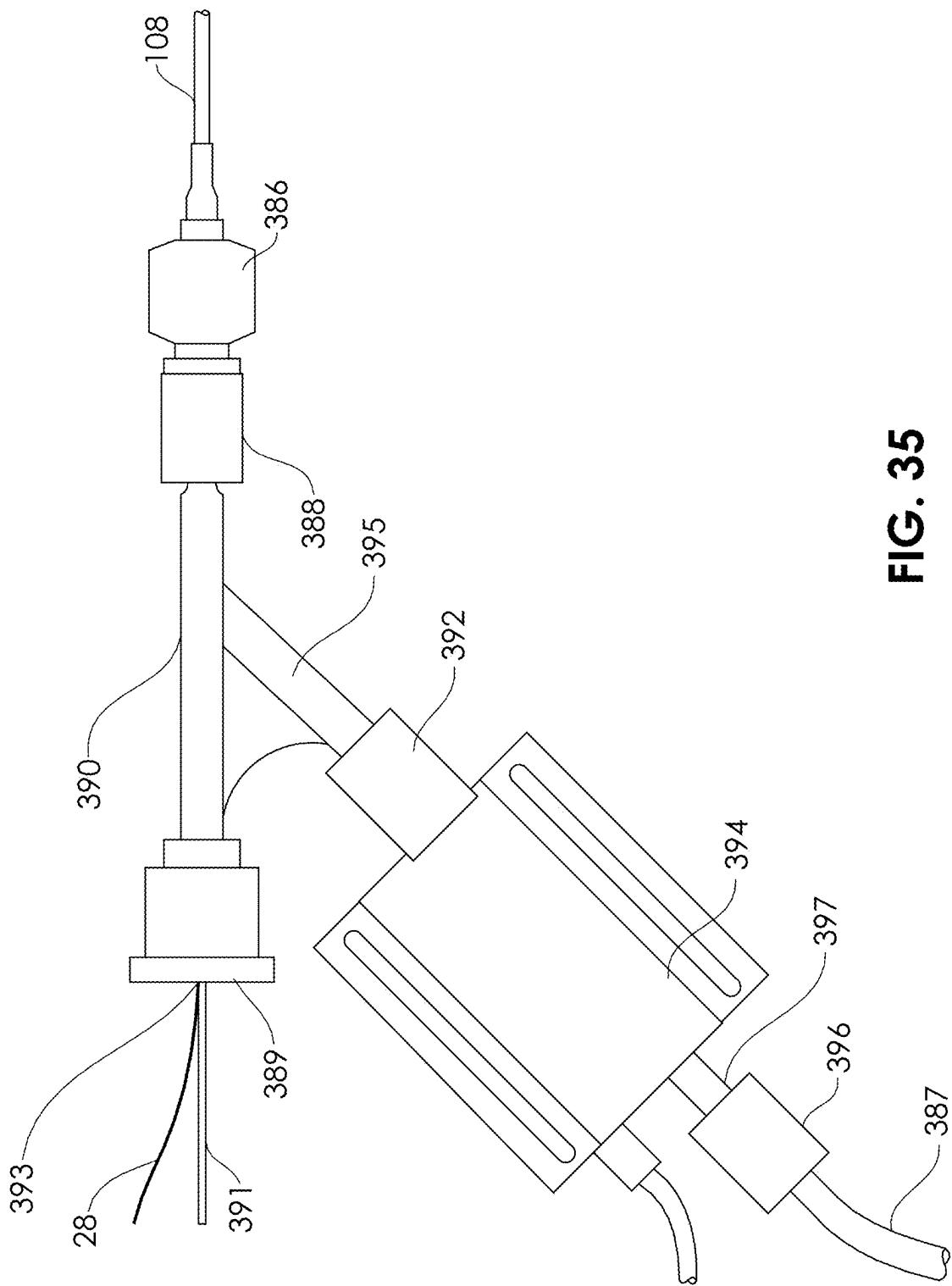
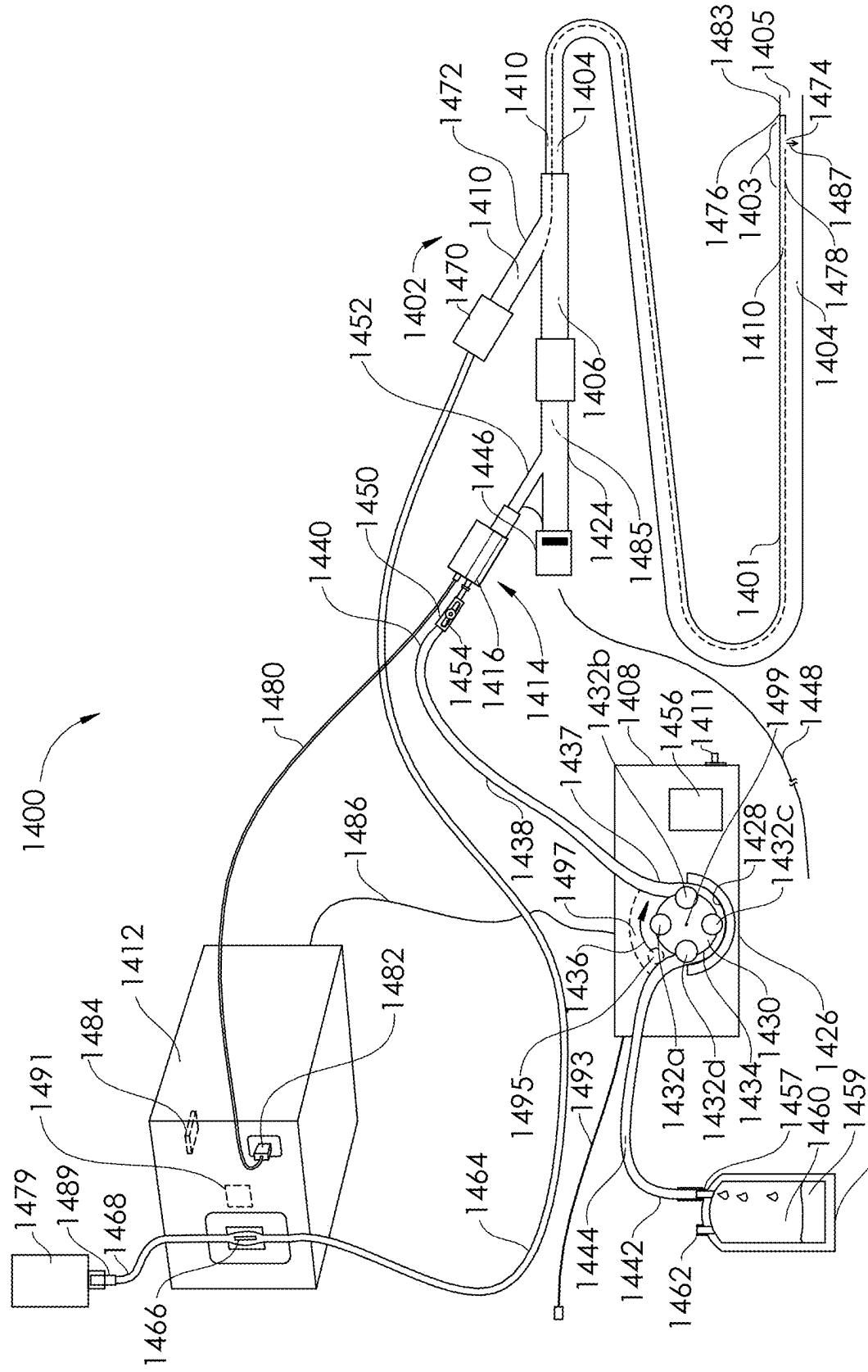


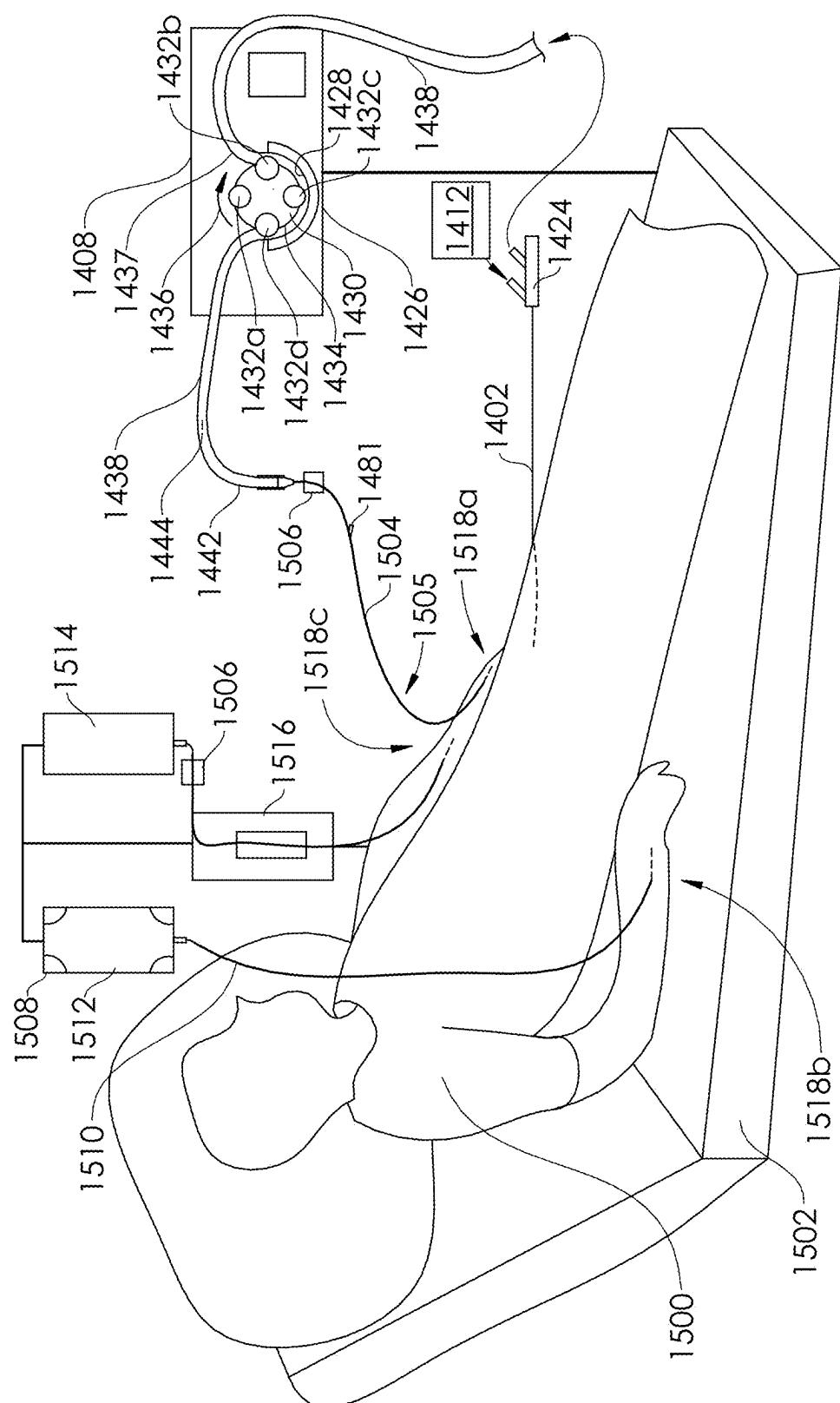
FIG. 34



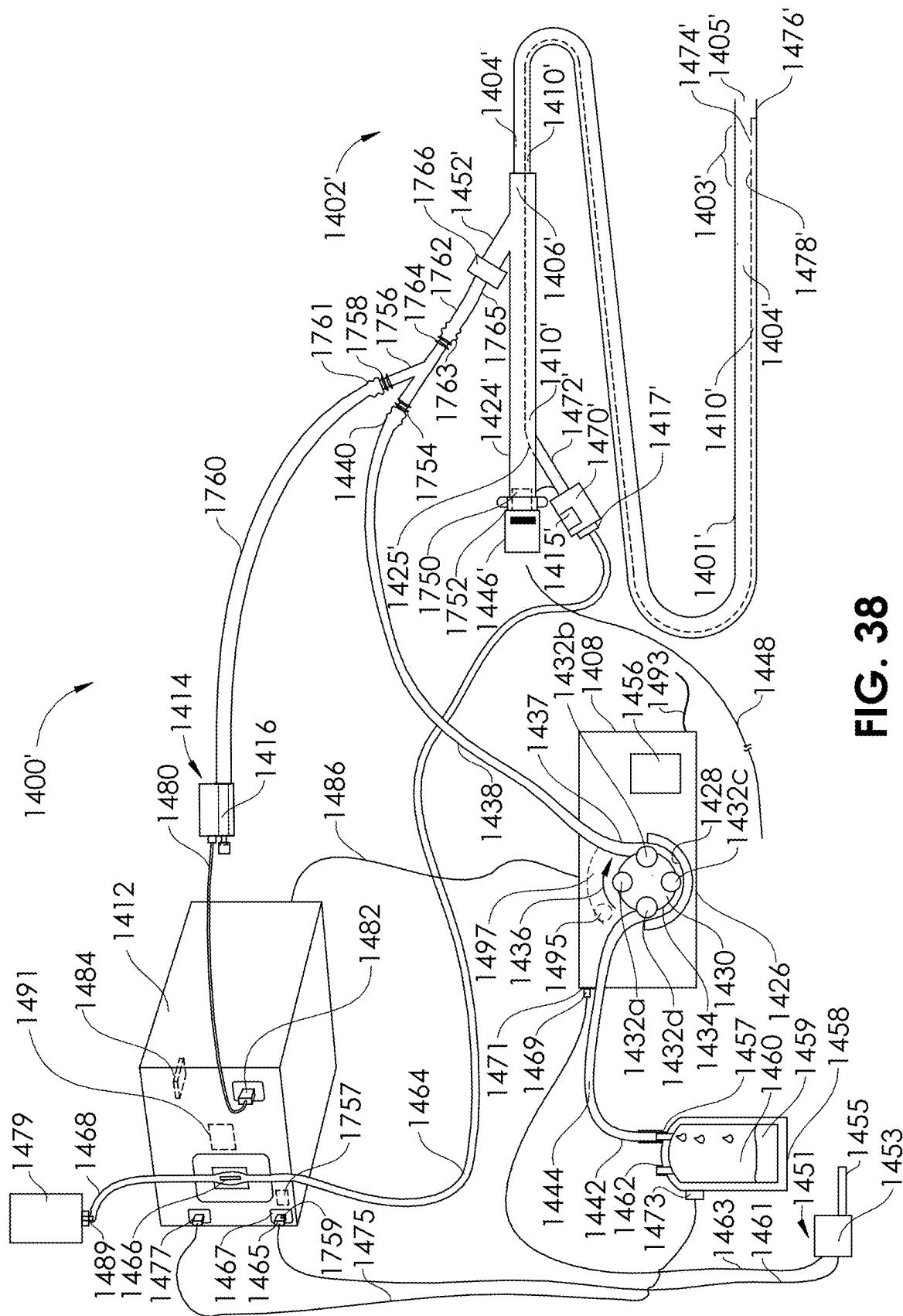
**FIG. 35**



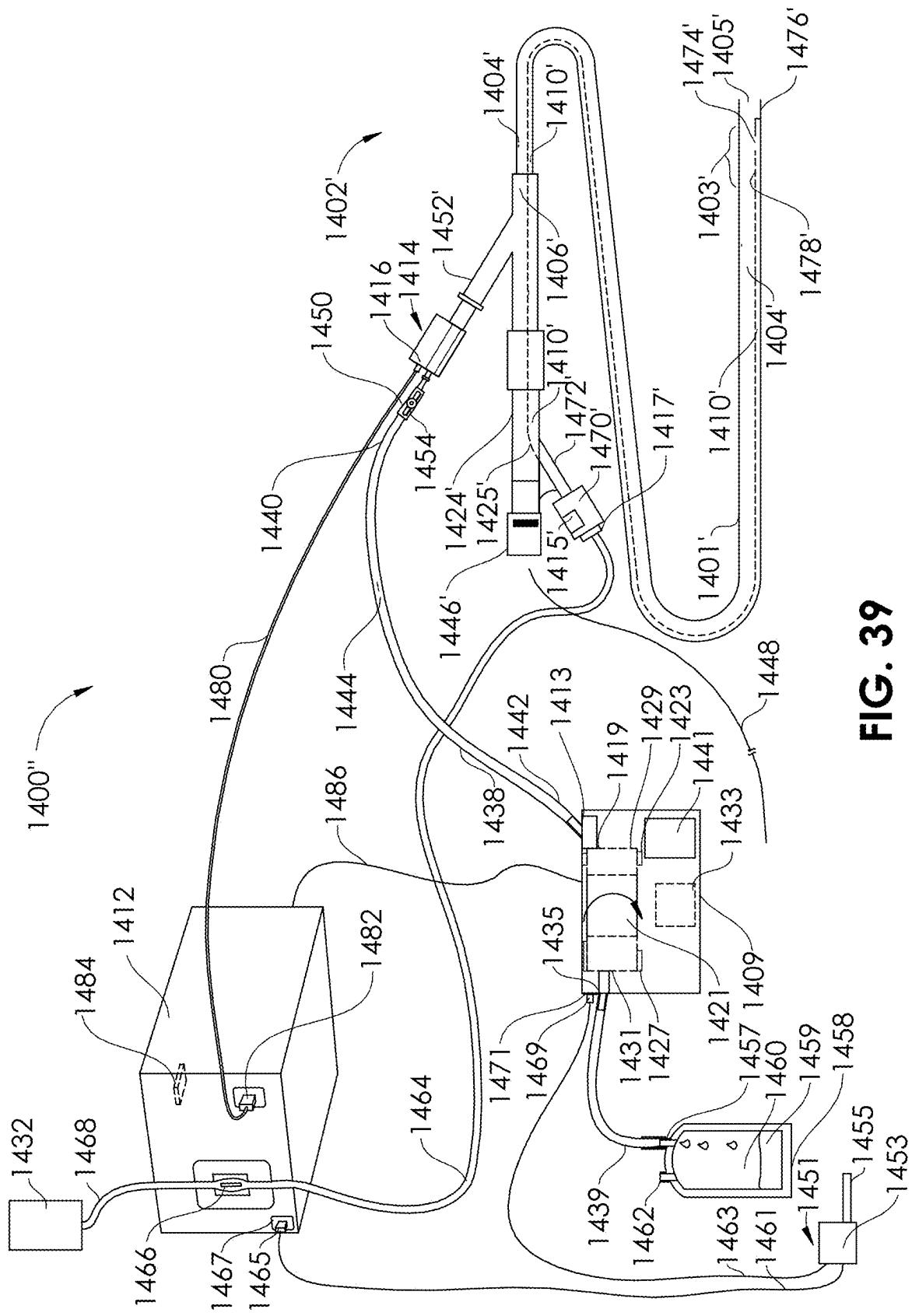
**FIG. 36**



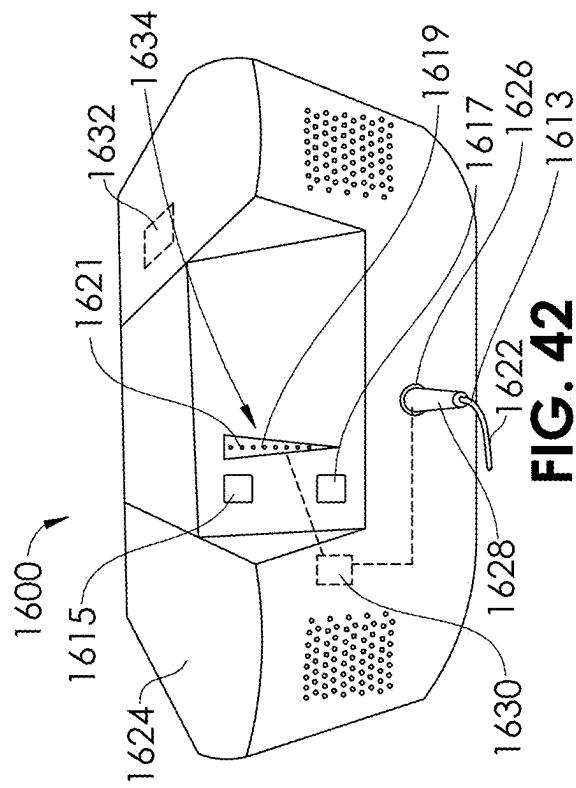
**FIG. 37**



**FIG. 38**



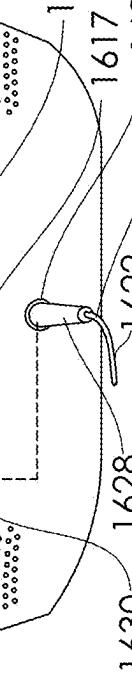
**FIG. 39**



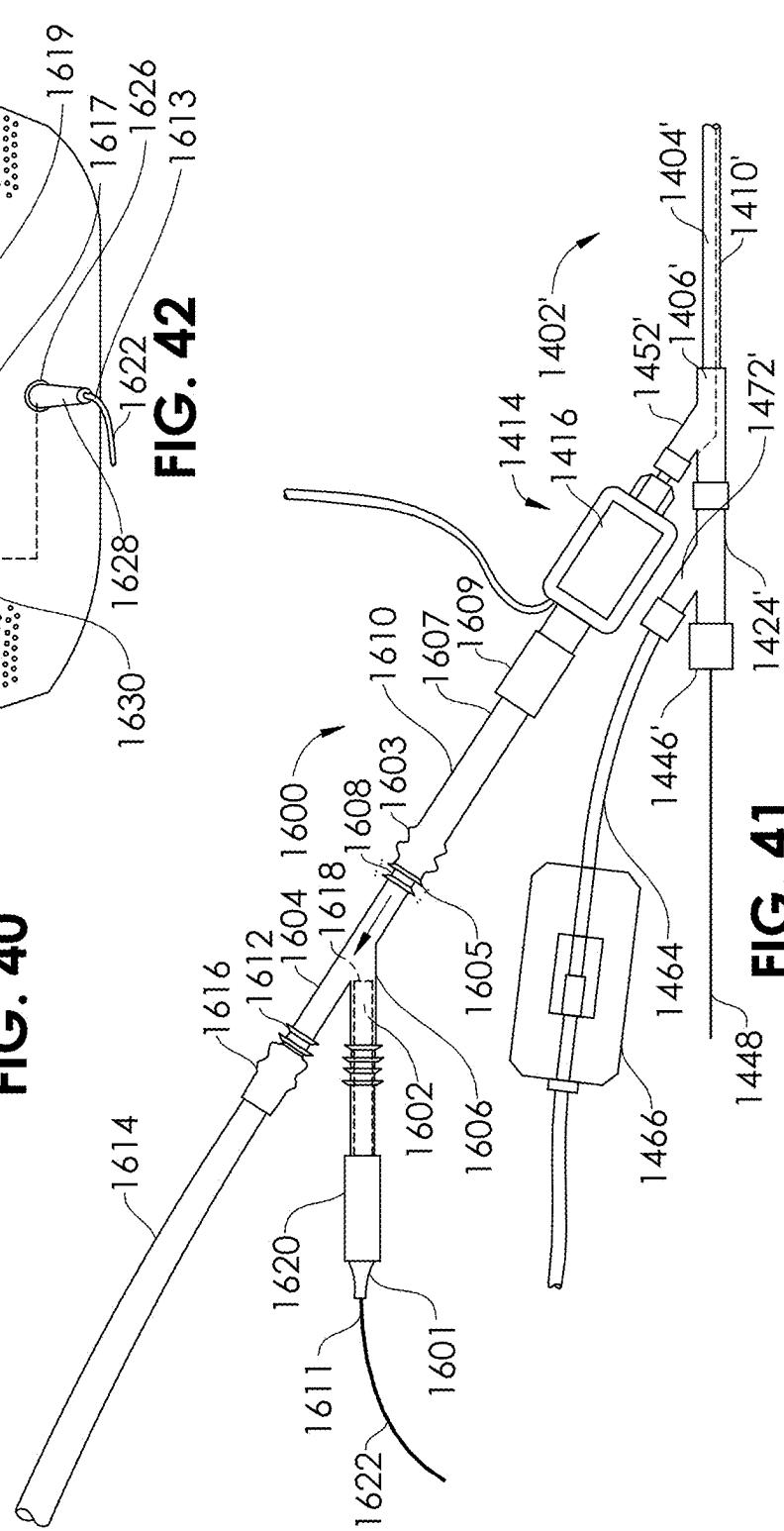
**FIG. 40**

**FIG. 42**

1619  
1617  
1626  
1613  
1622  
1628  
1630



**FIG. 42**



**FIG. 41**

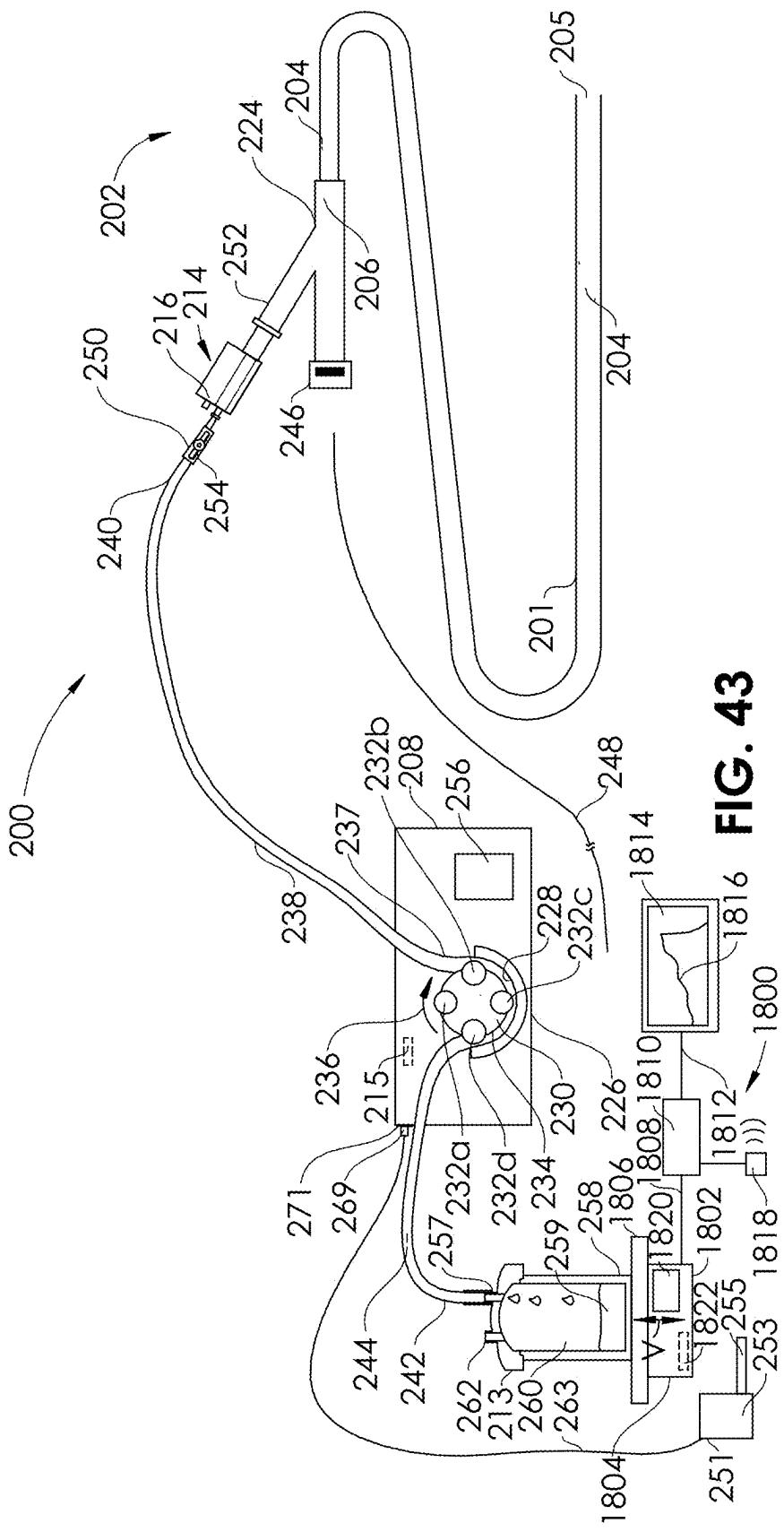
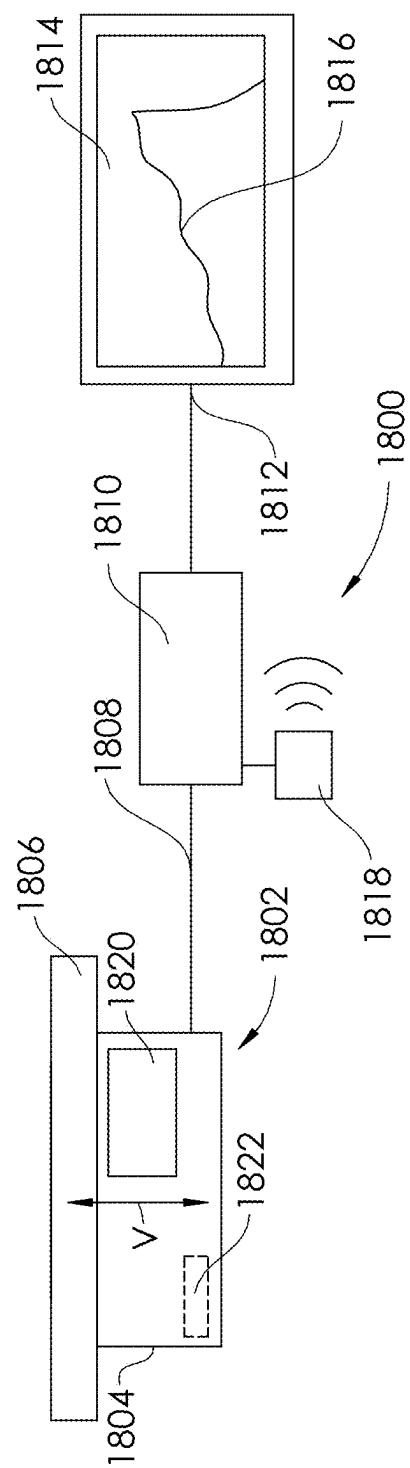
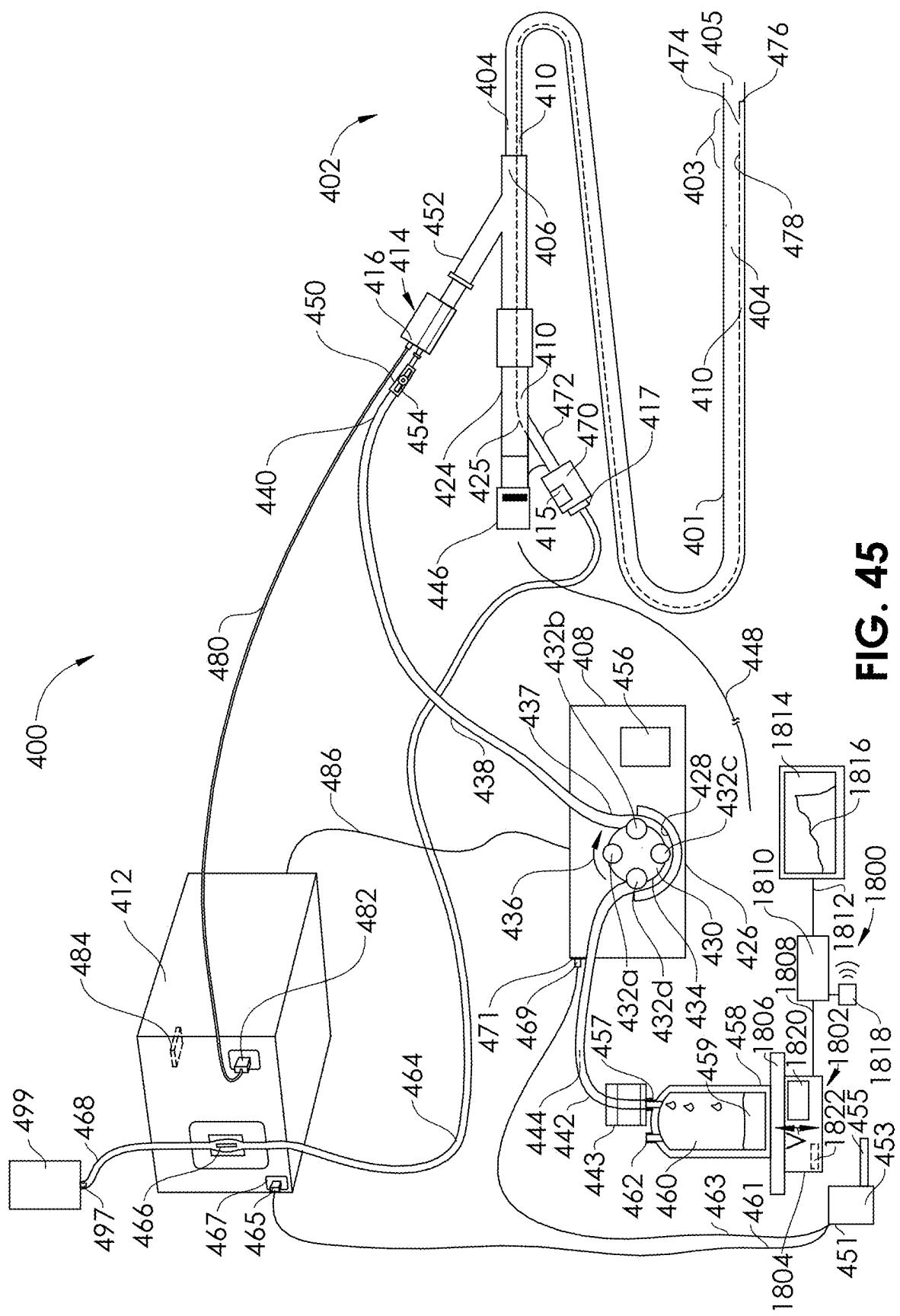
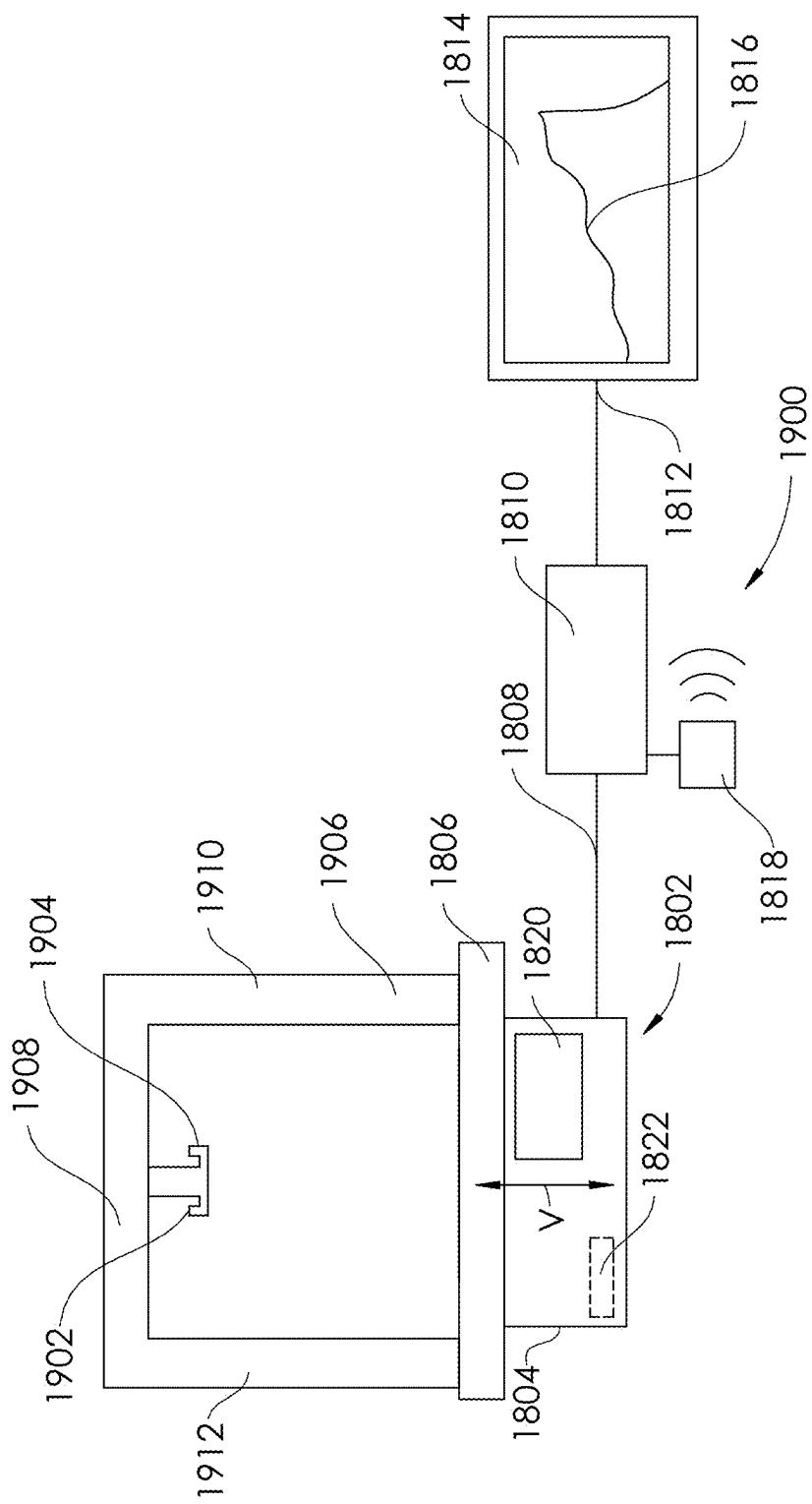


FIG. 43

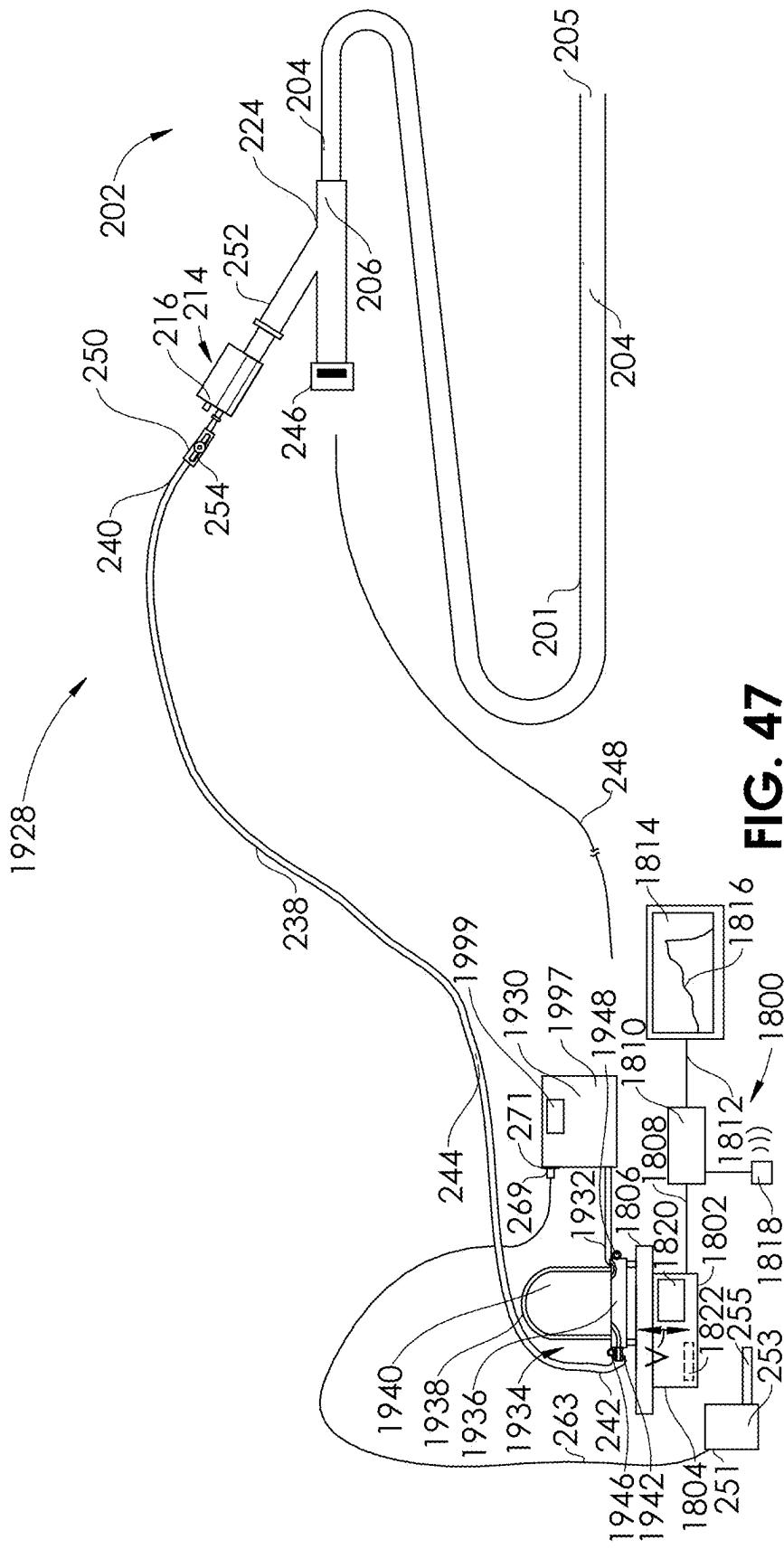


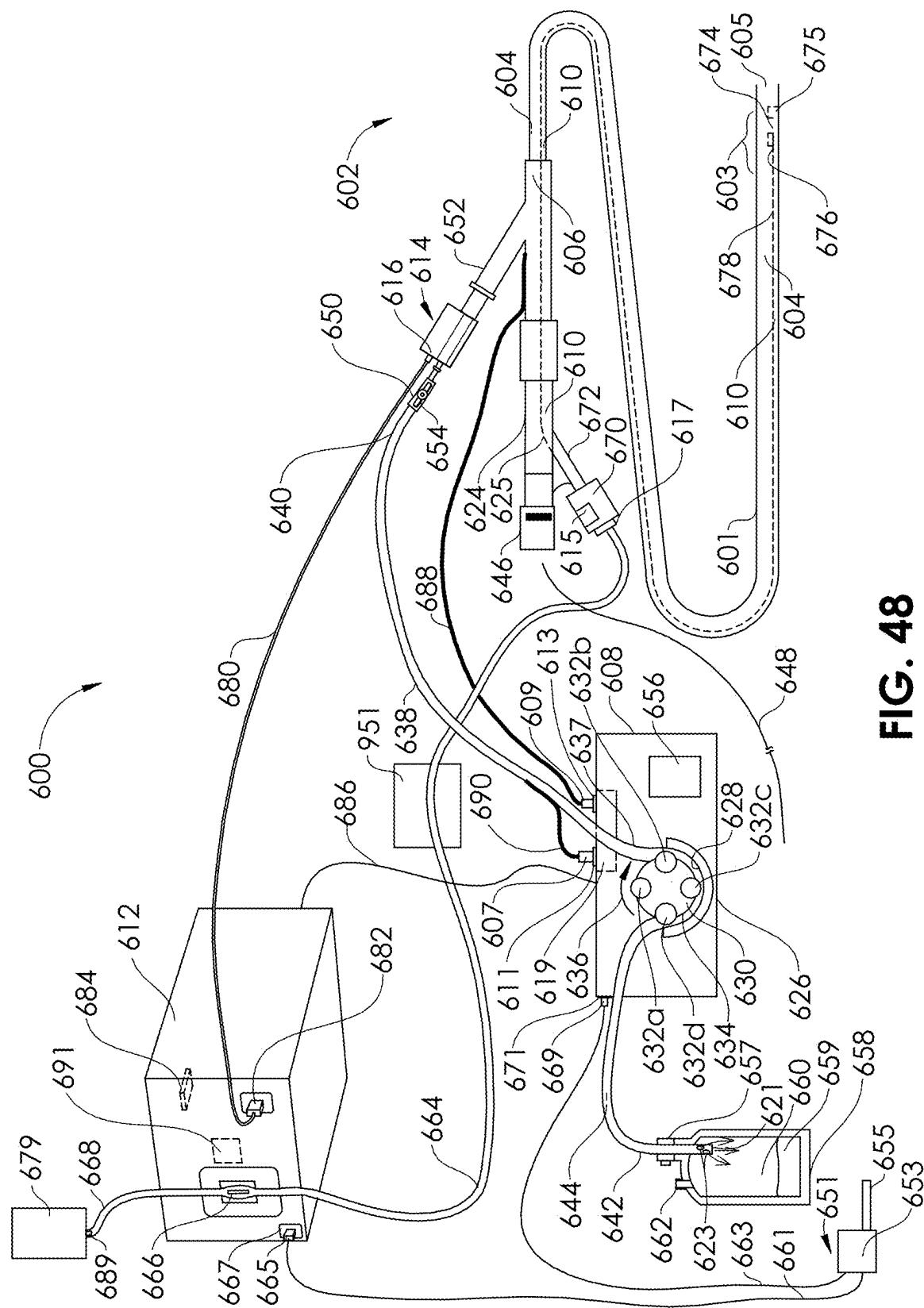
**FIG. 44**



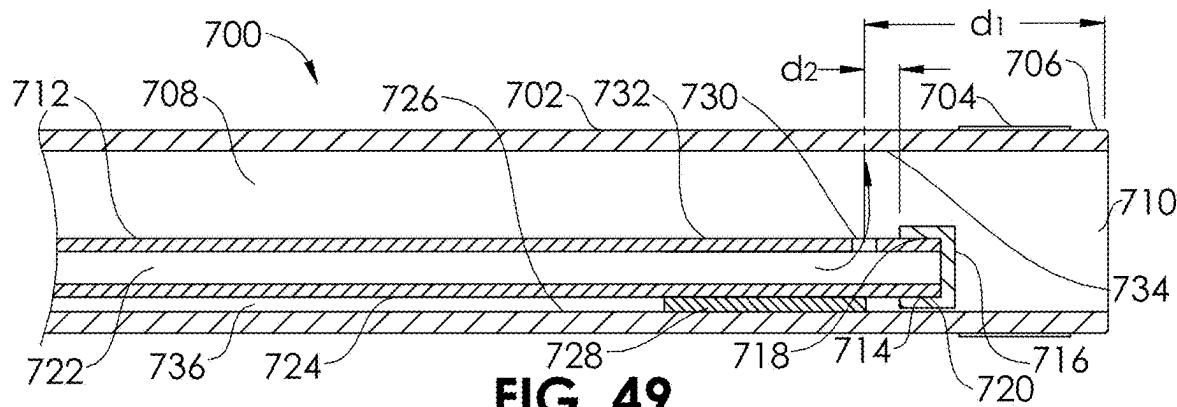


**FIG. 46**

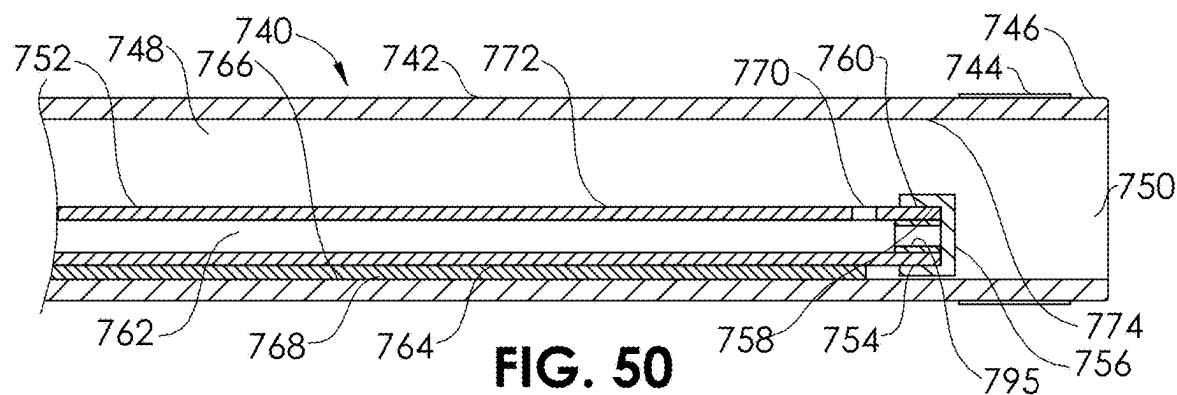




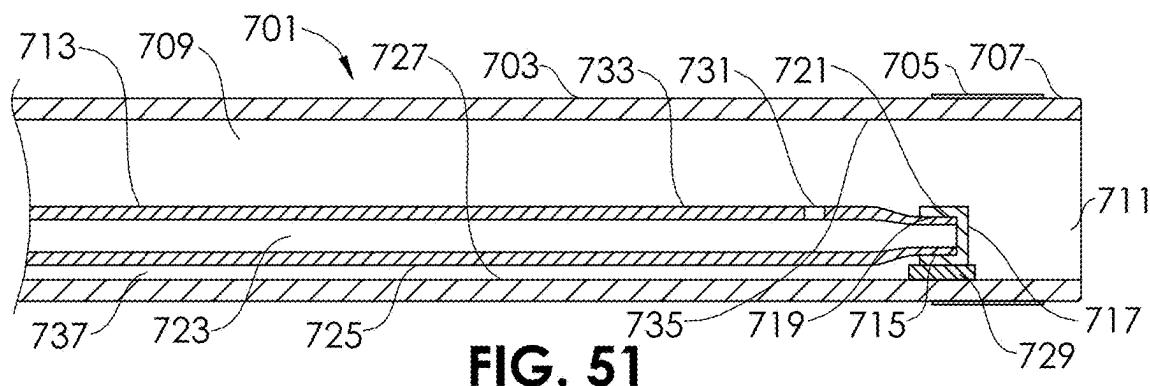
**FIG. 48**



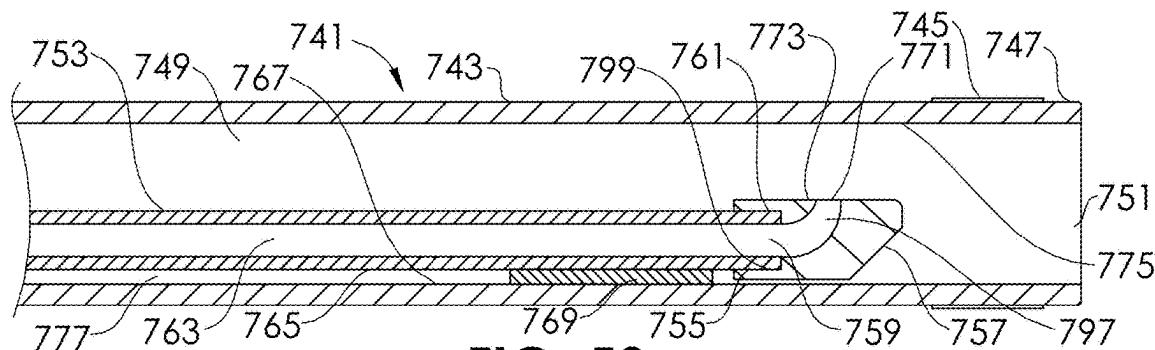
**FIG. 49**



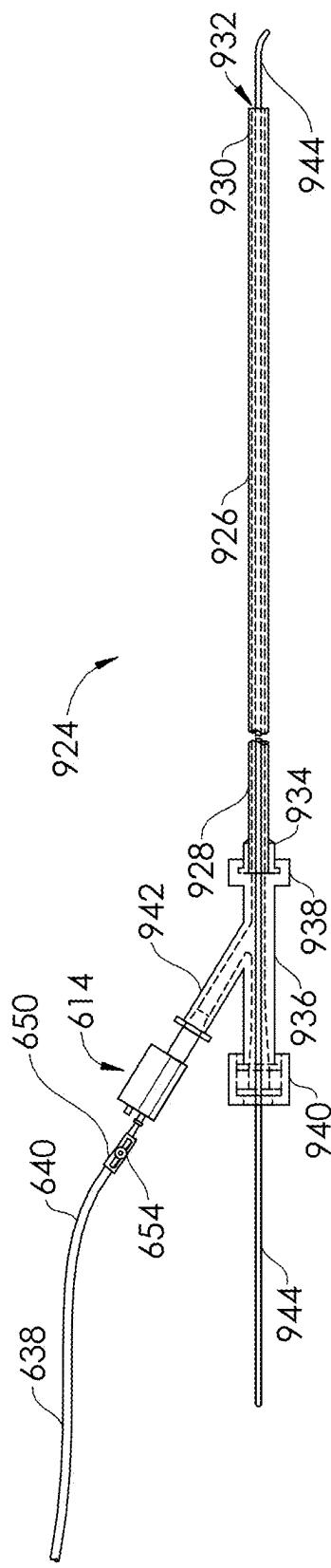
**FIG. 50**



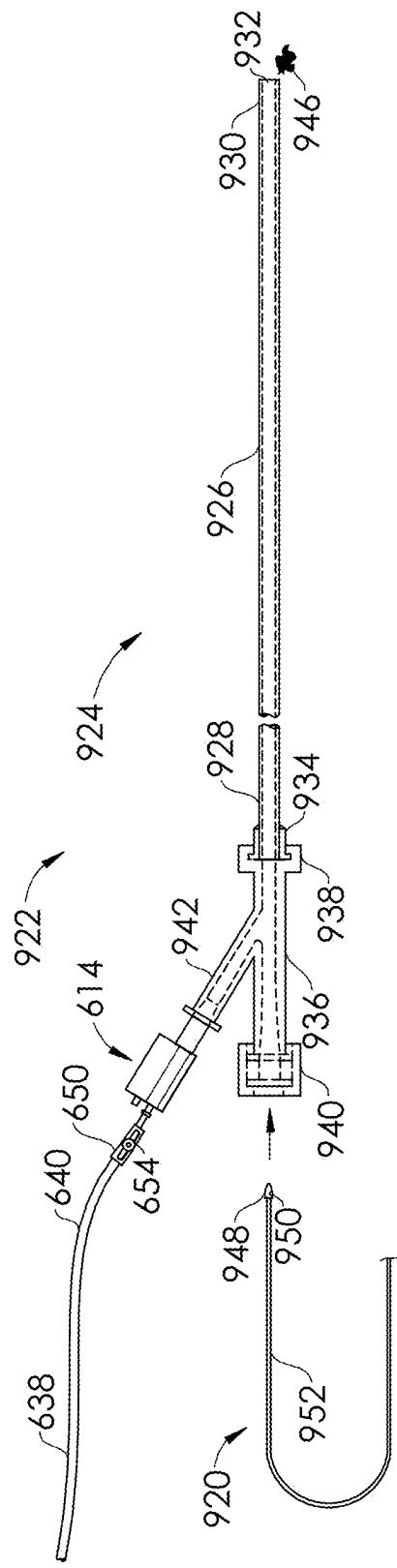
**FIG. 51**



**FIG. 52**



**FIG. 53**



**FIG. 54**

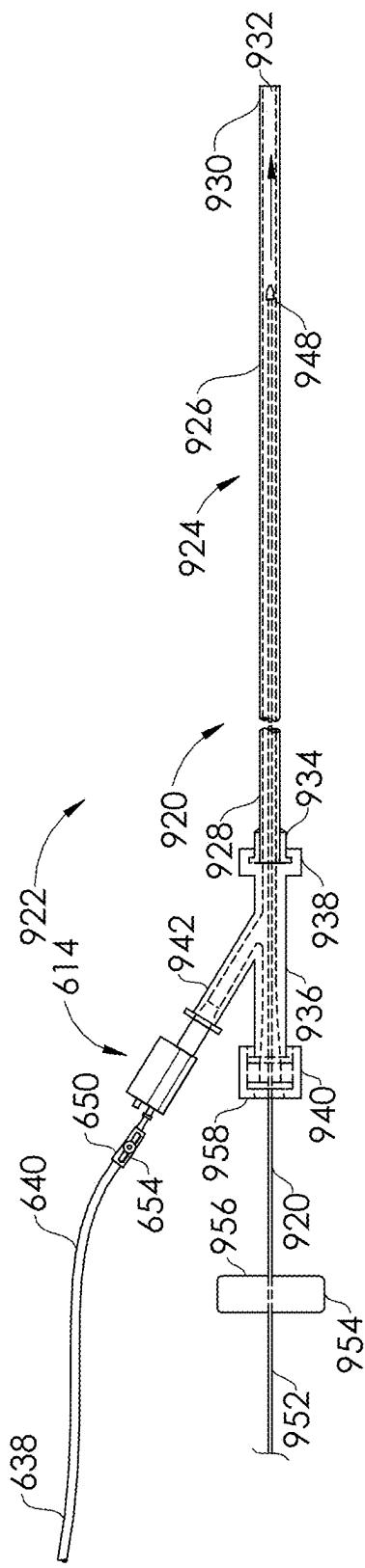


FIG. 55

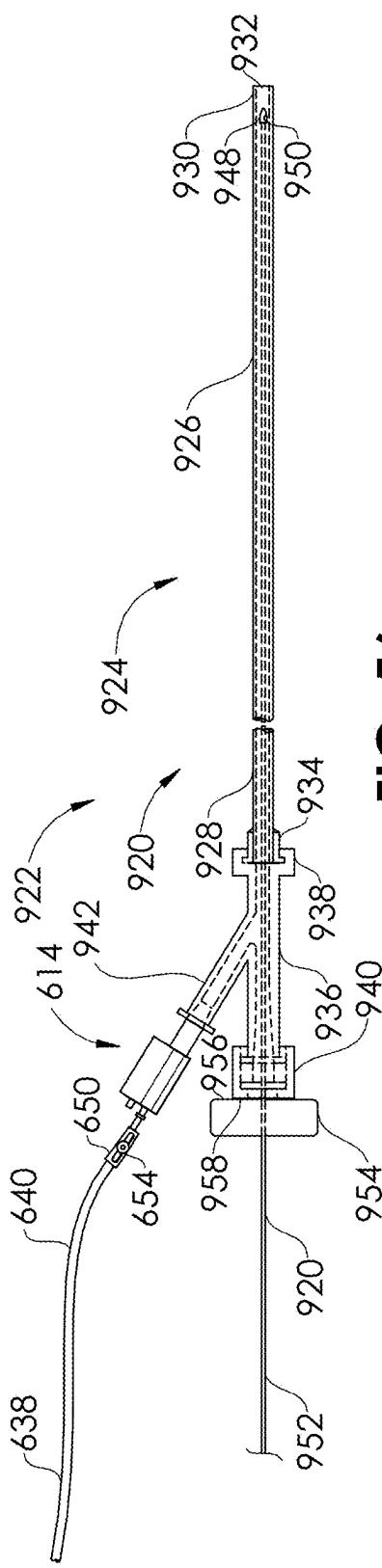
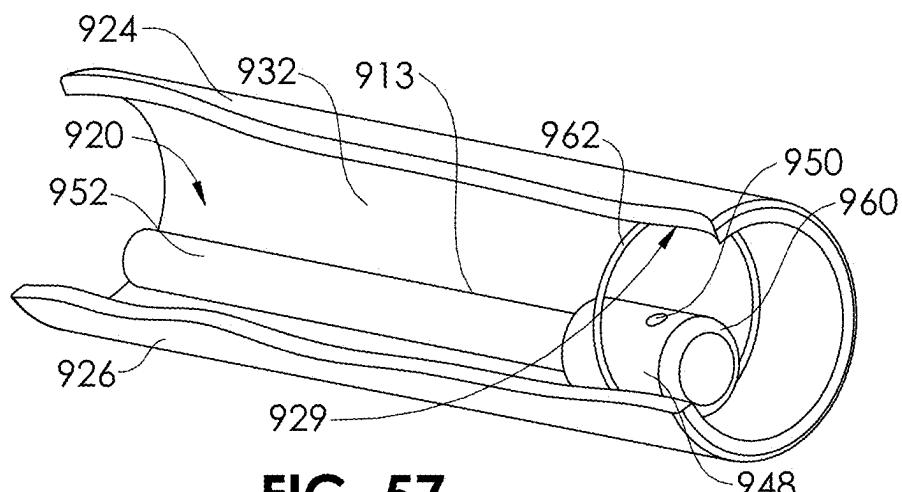
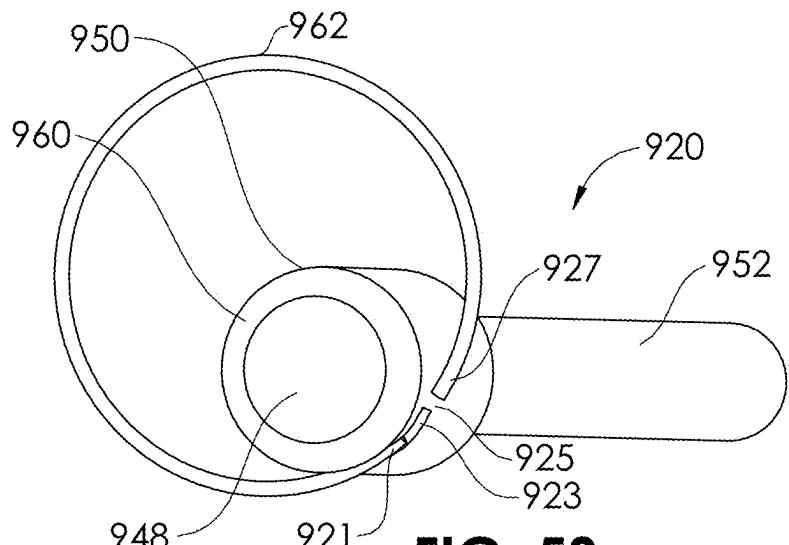


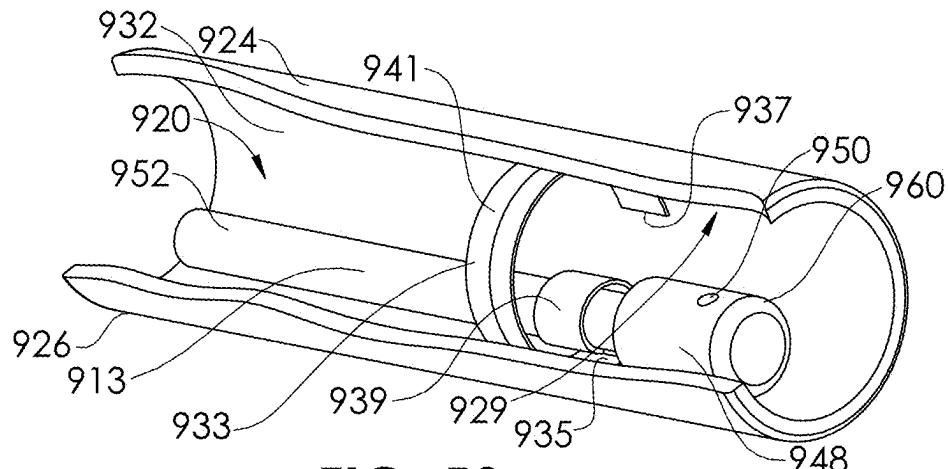
FIG. 56



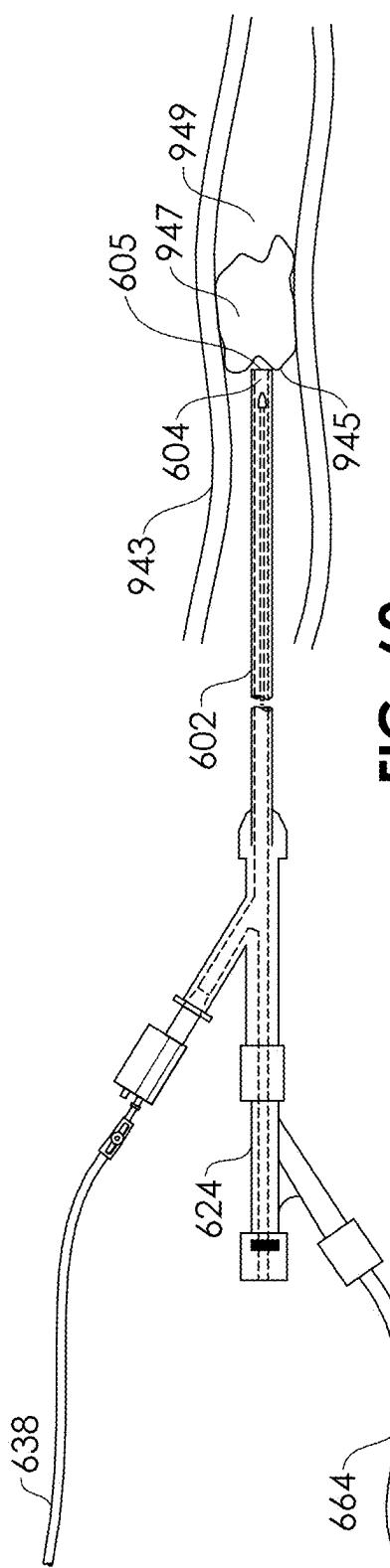
**FIG. 57**



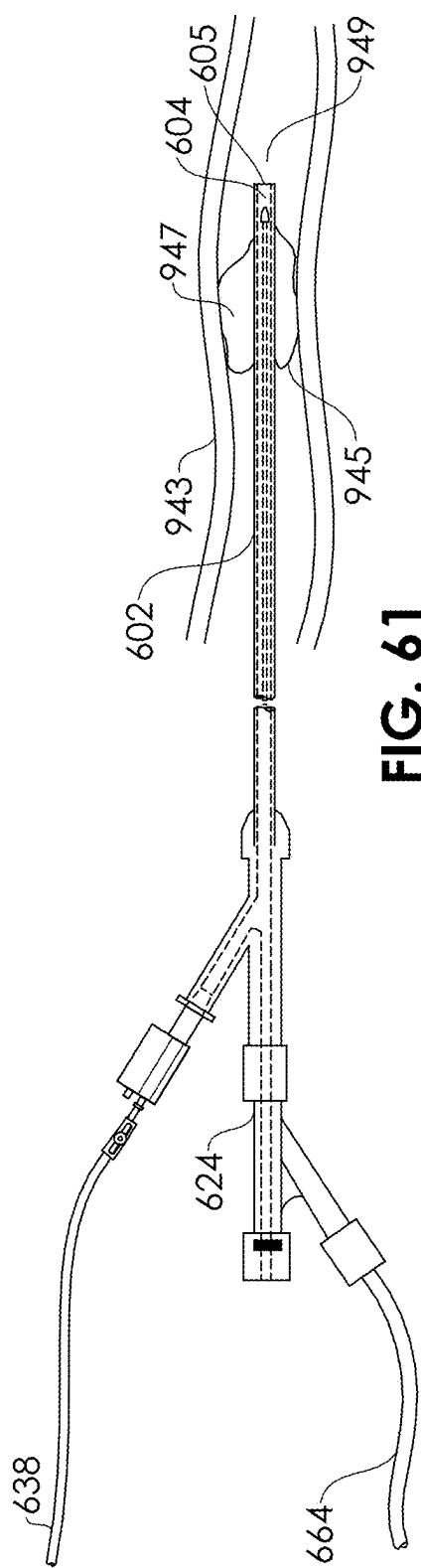
**FIG. 58**



**FIG. 59**



**FIG. 60**



**FIG. 61**

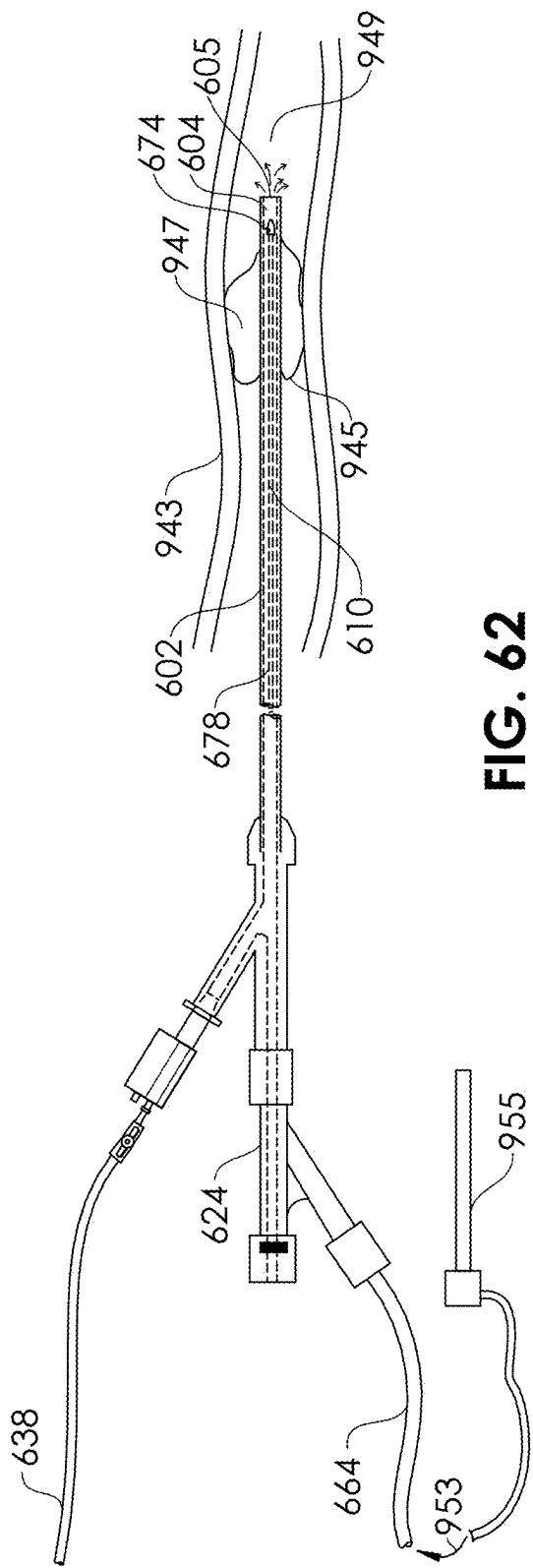


FIG. 62

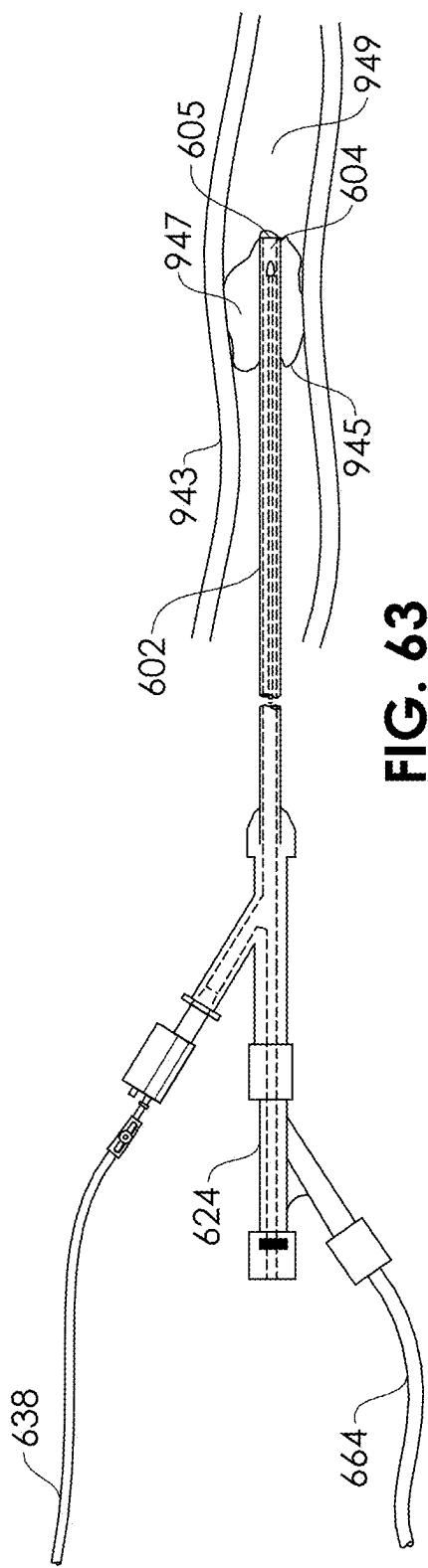
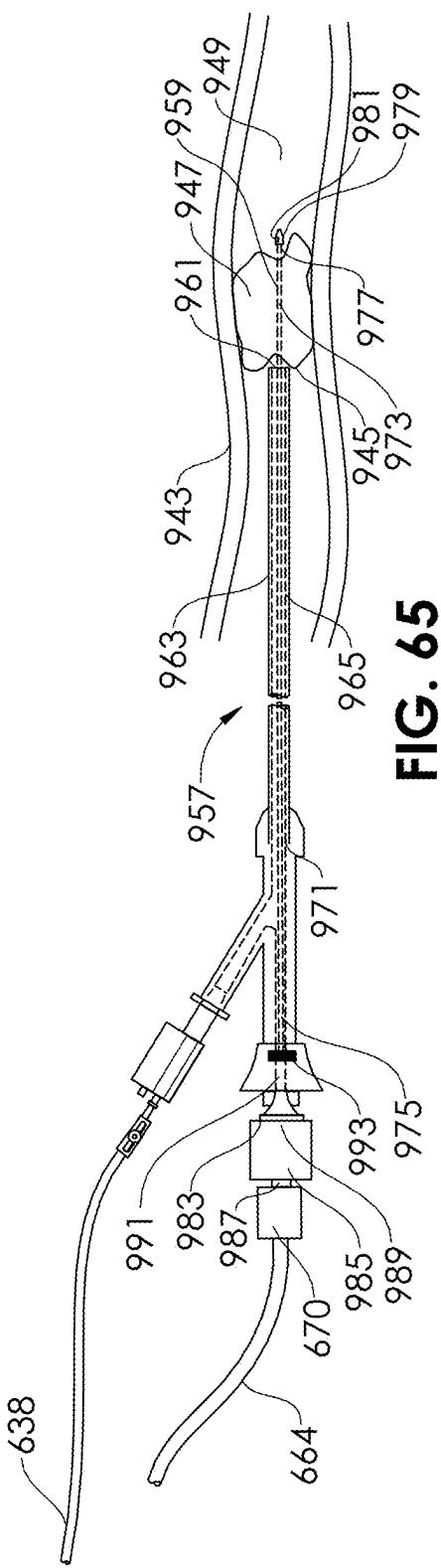
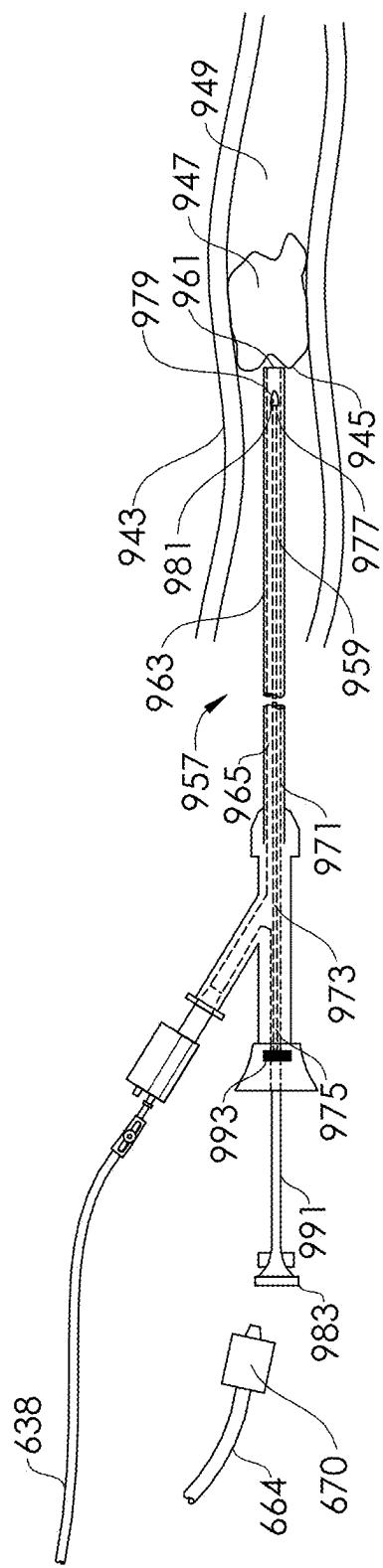
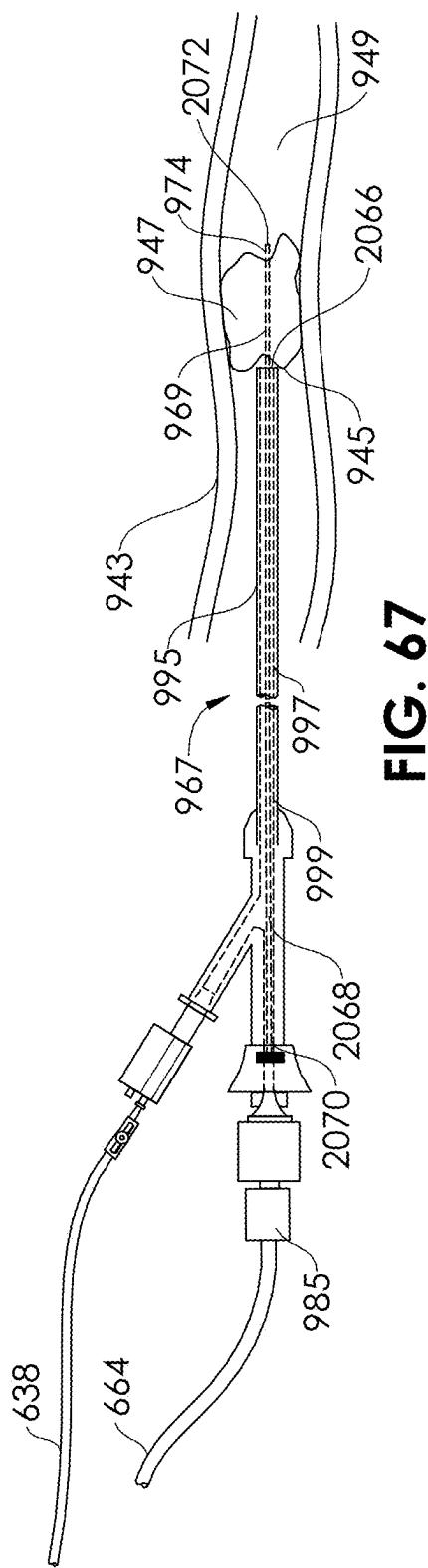
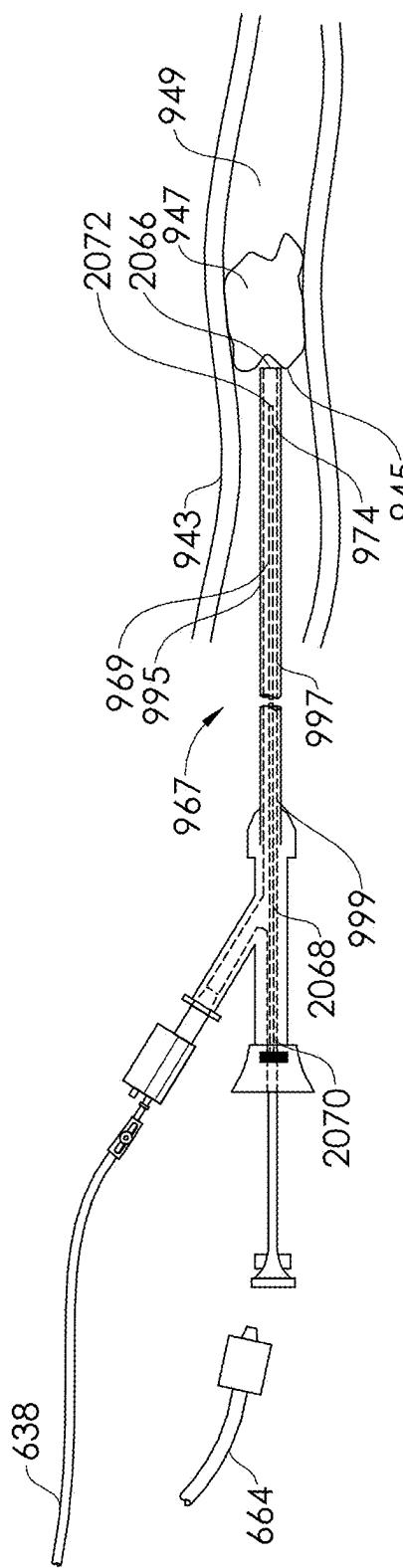
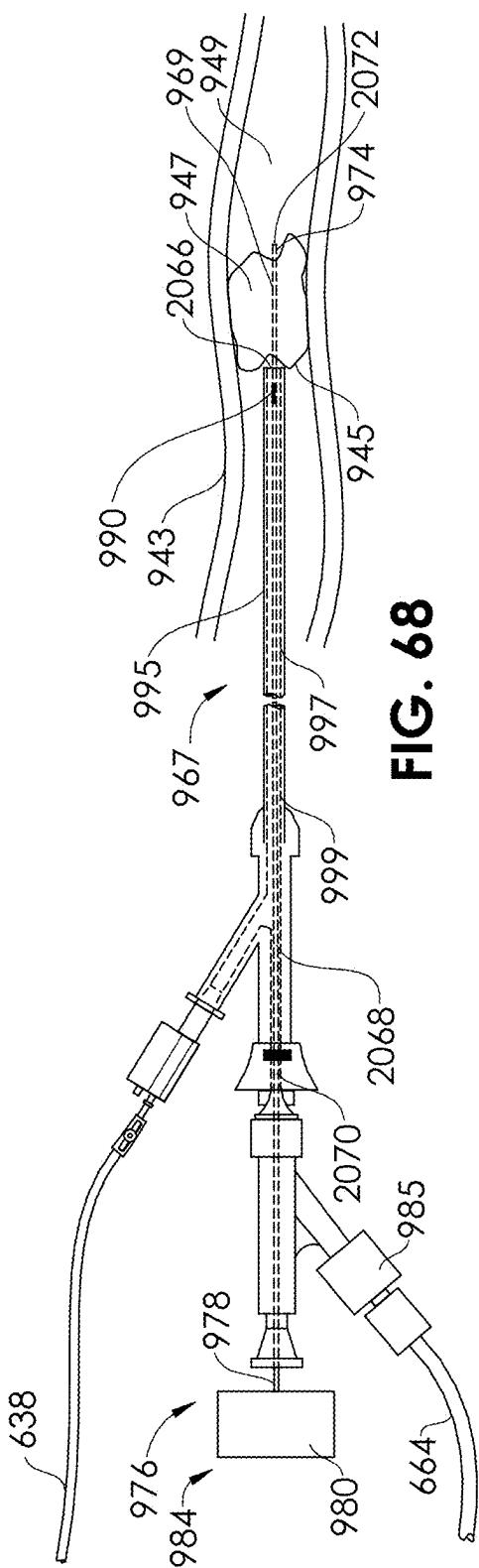


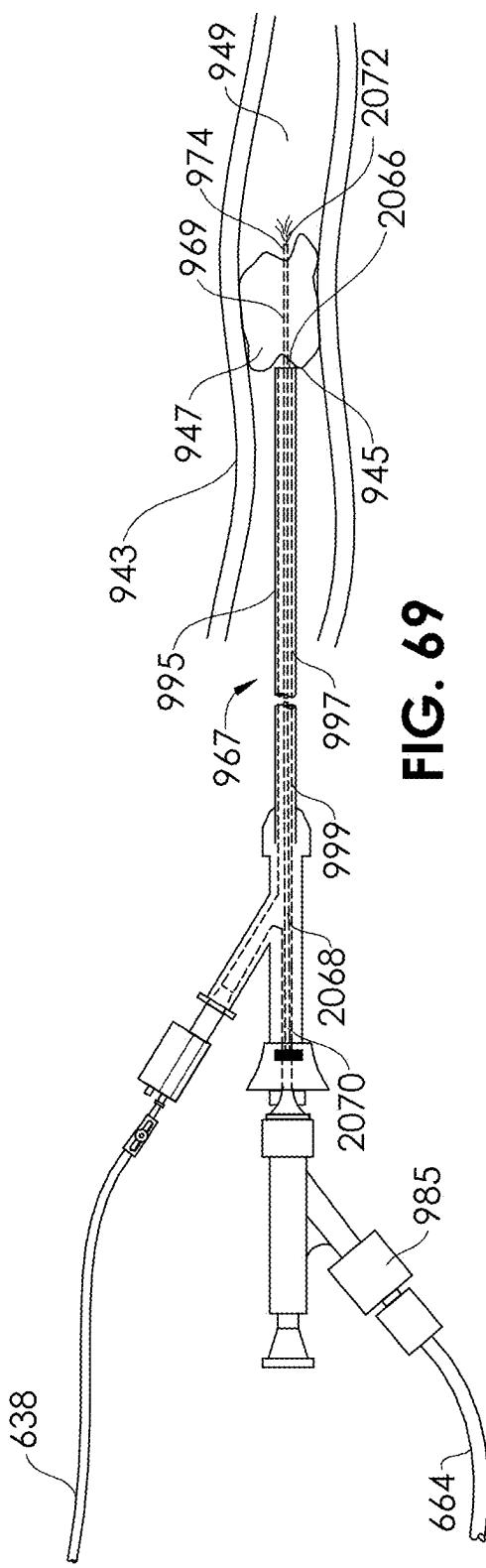
FIG. 63







**FIG. 68**



**FIG. 69**

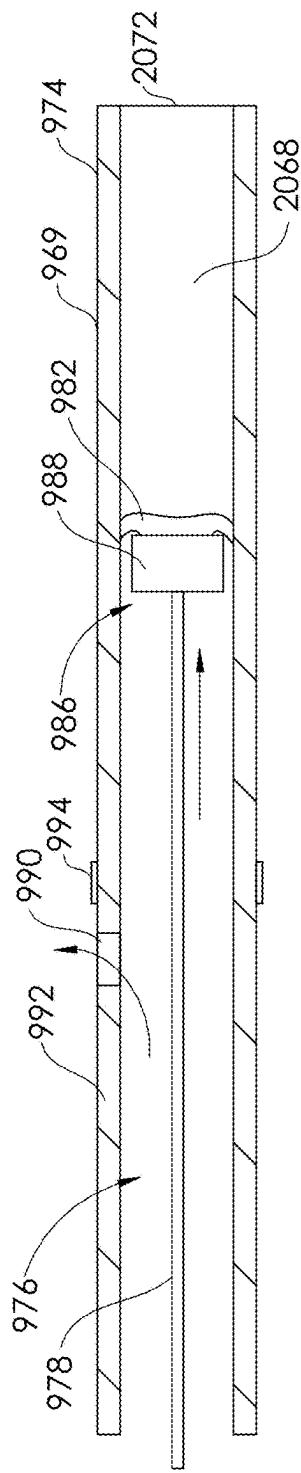


FIG. 70

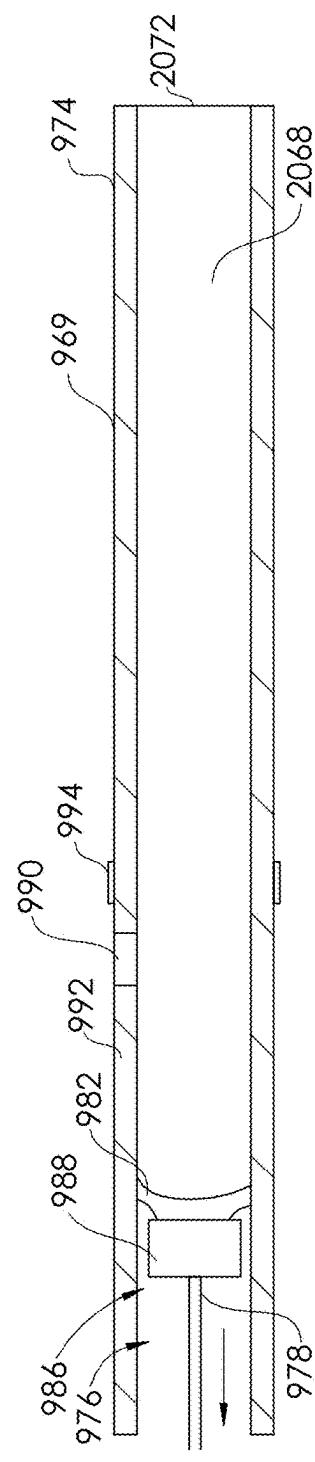


FIG. 71

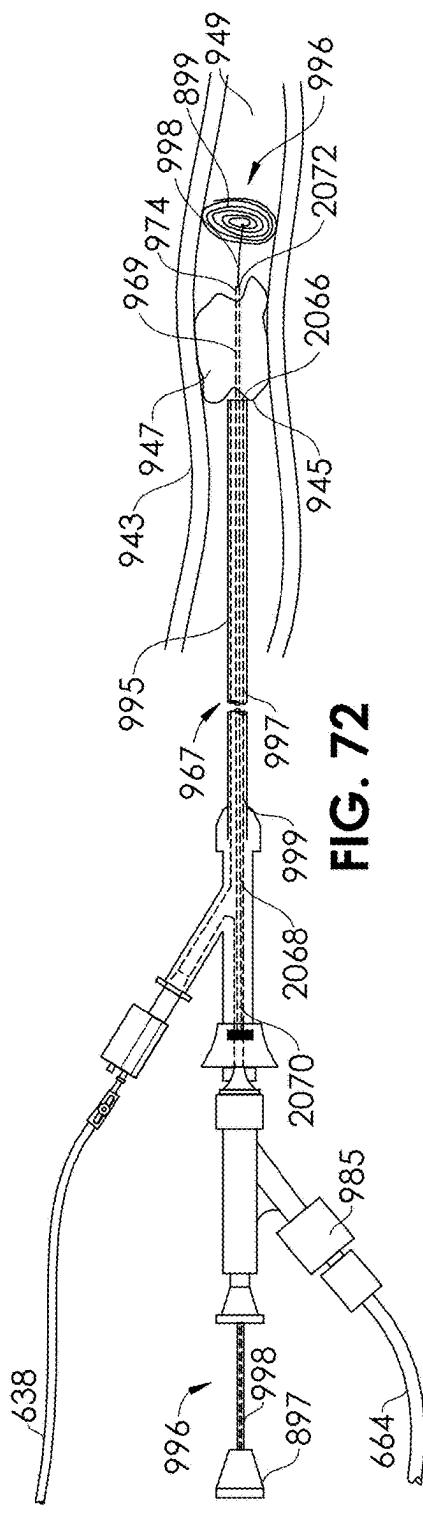
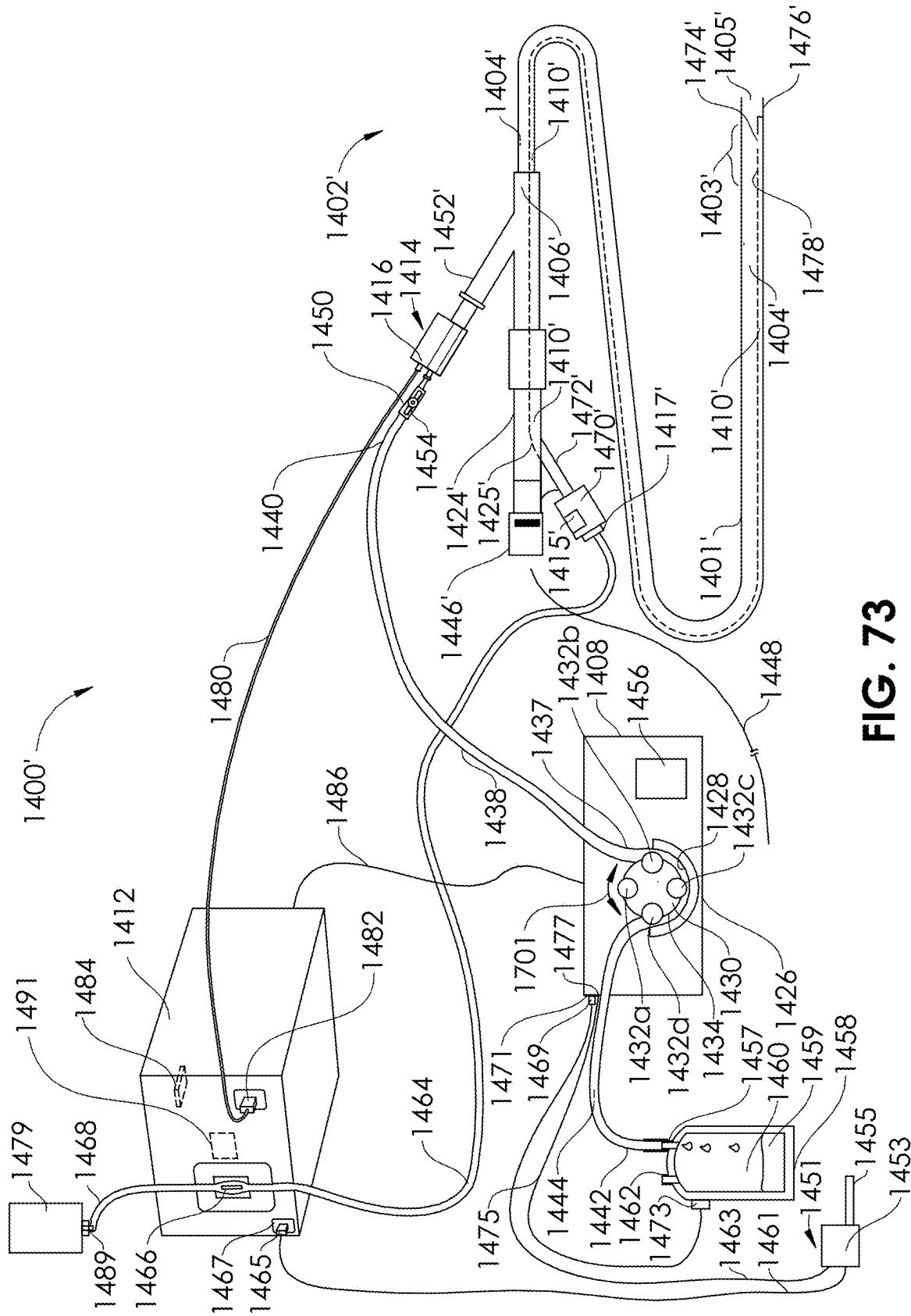
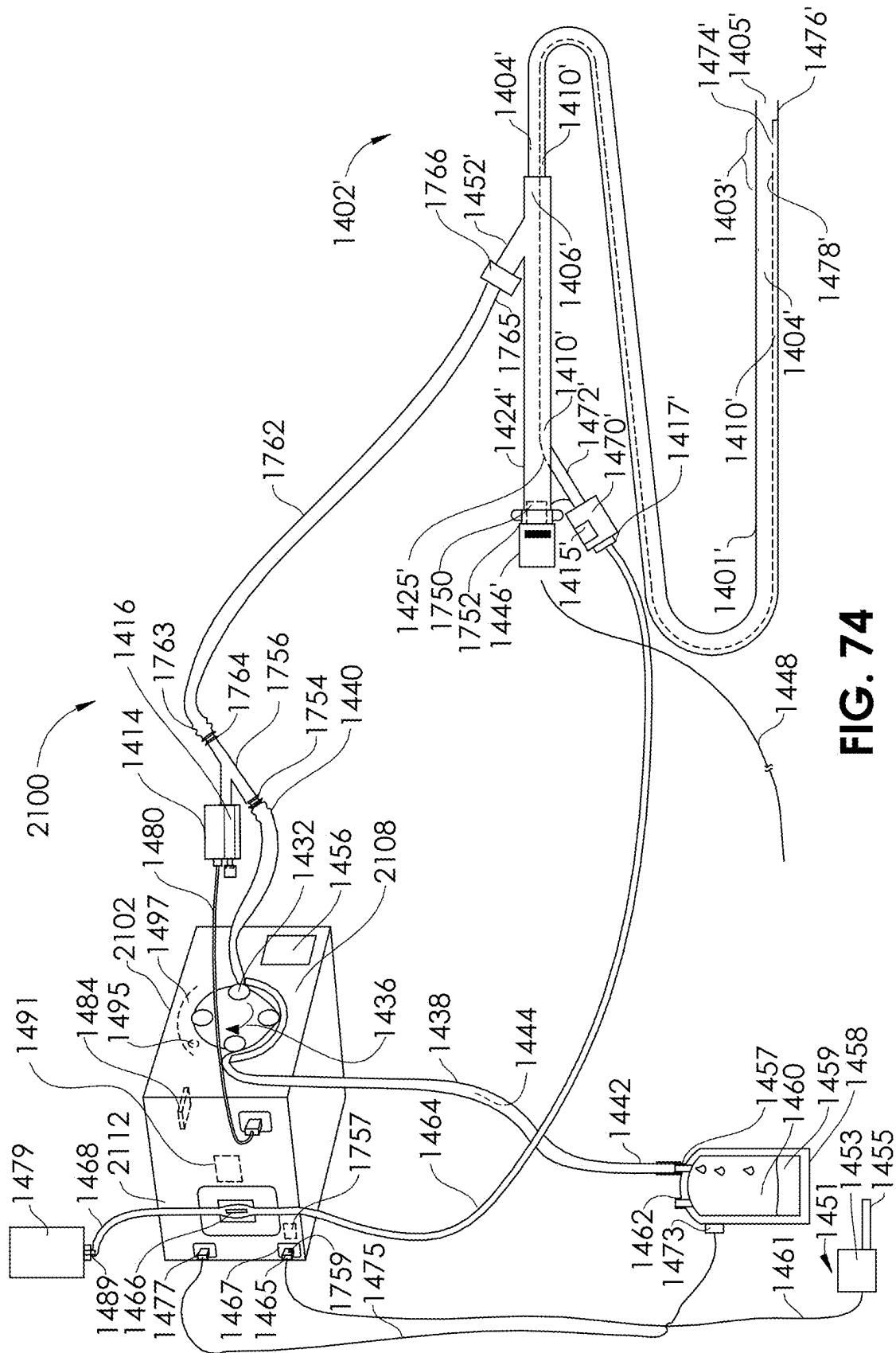
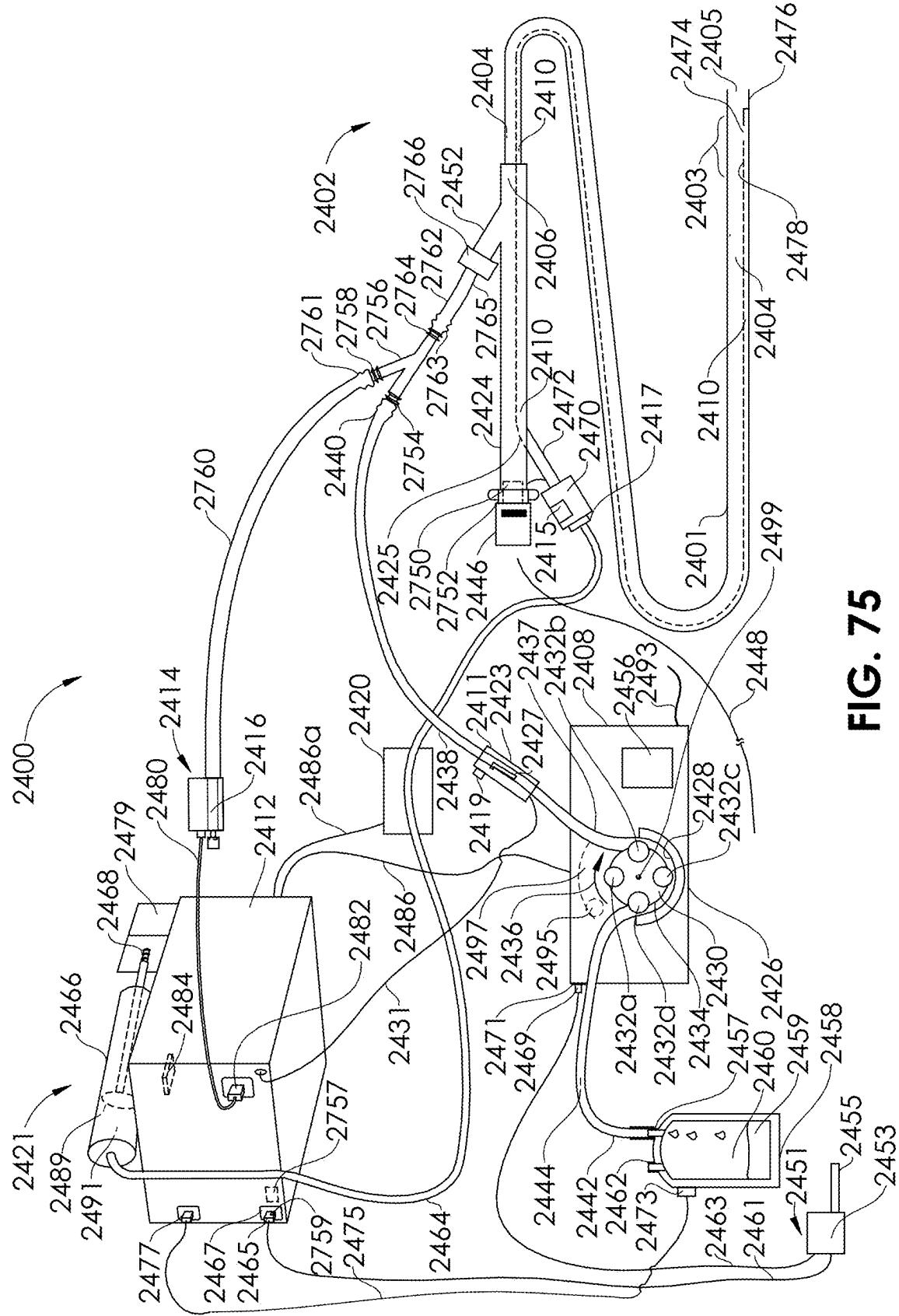


FIG. 72



**FIG. 73**





**FIG. 75**

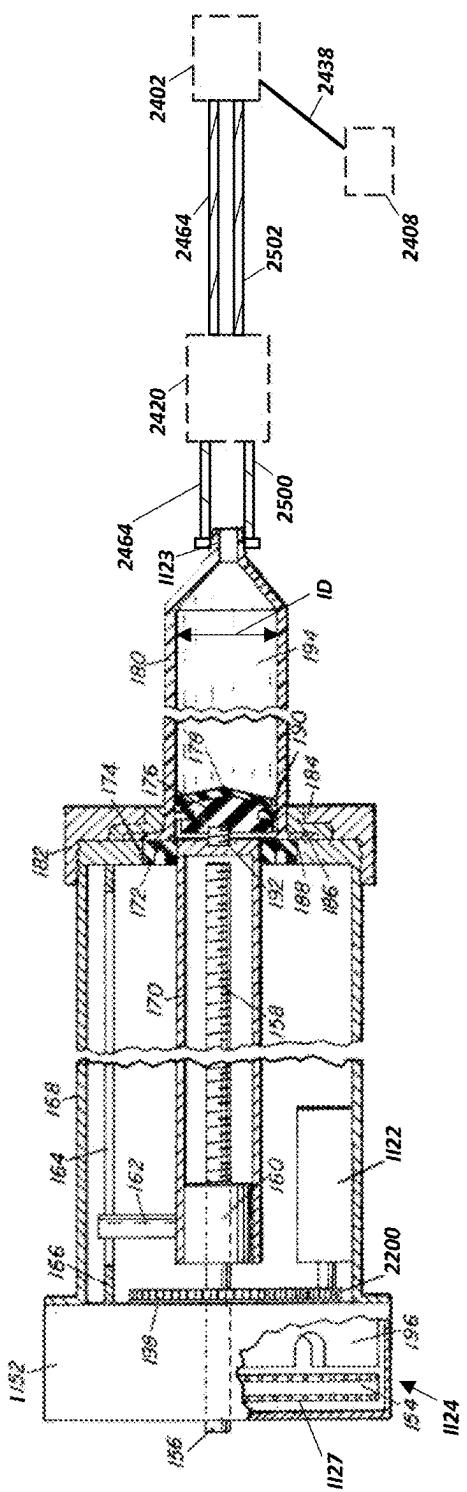
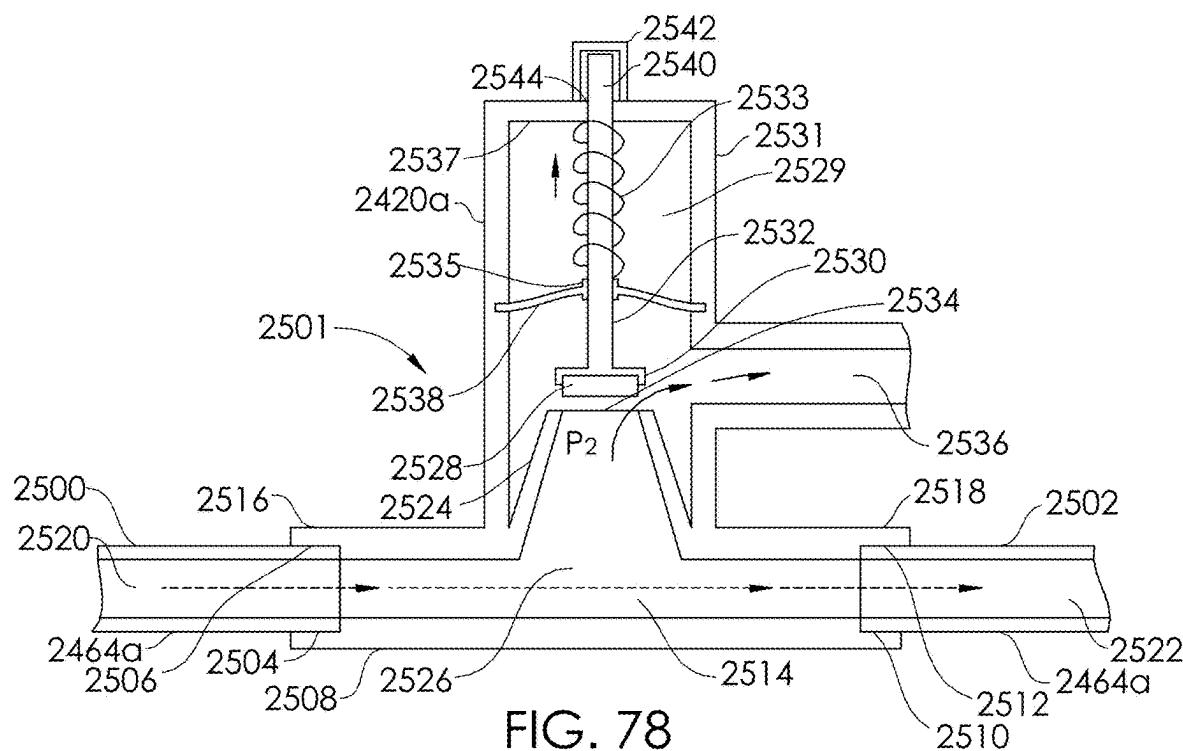
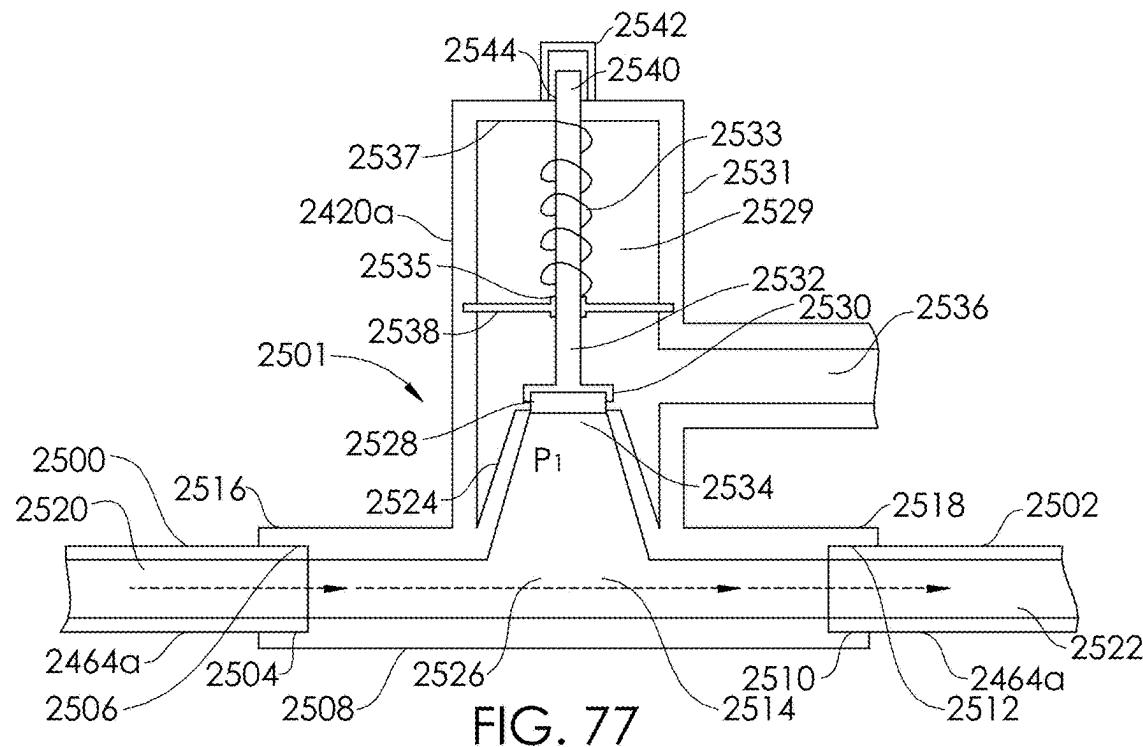
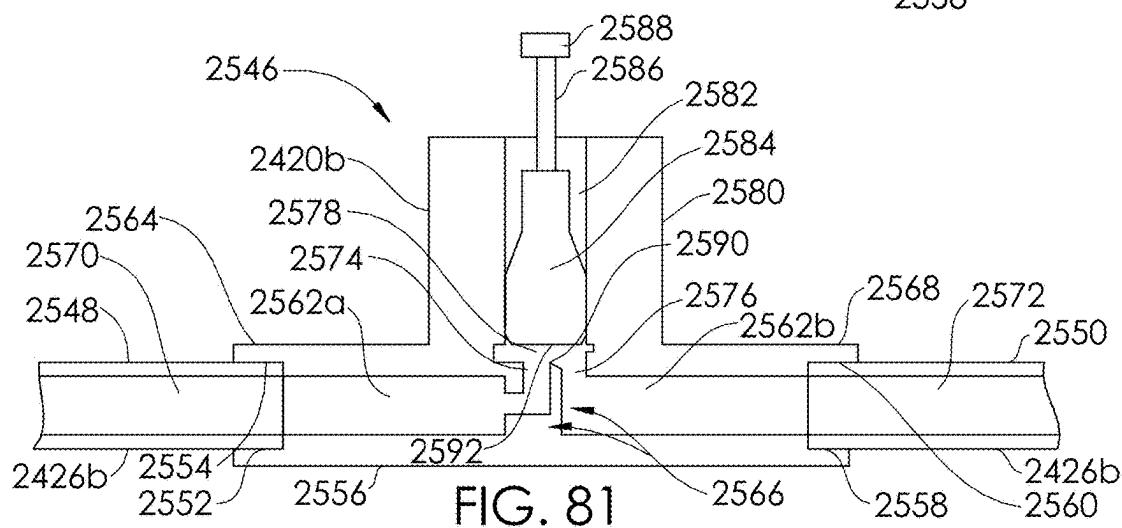
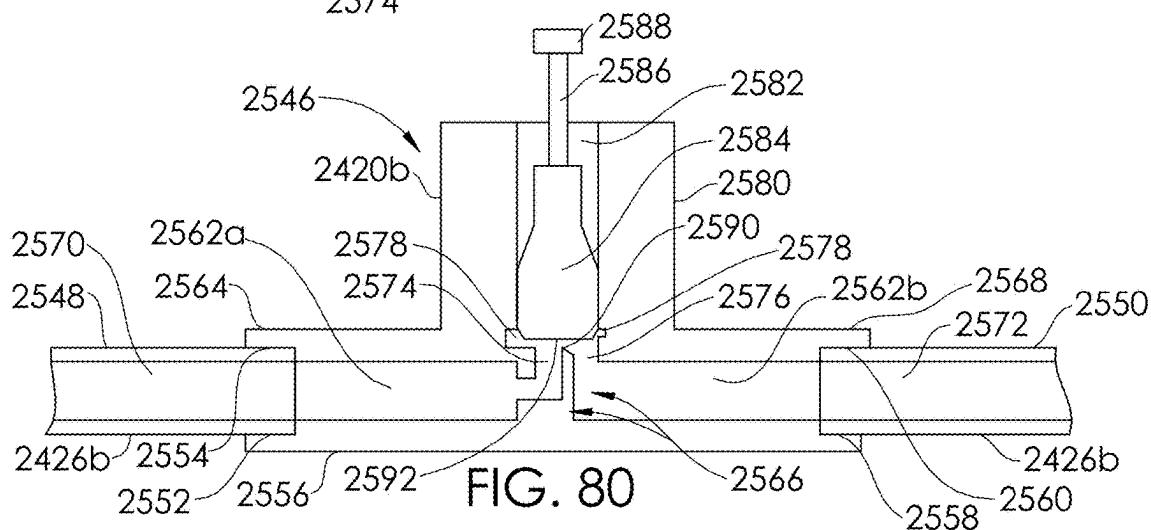
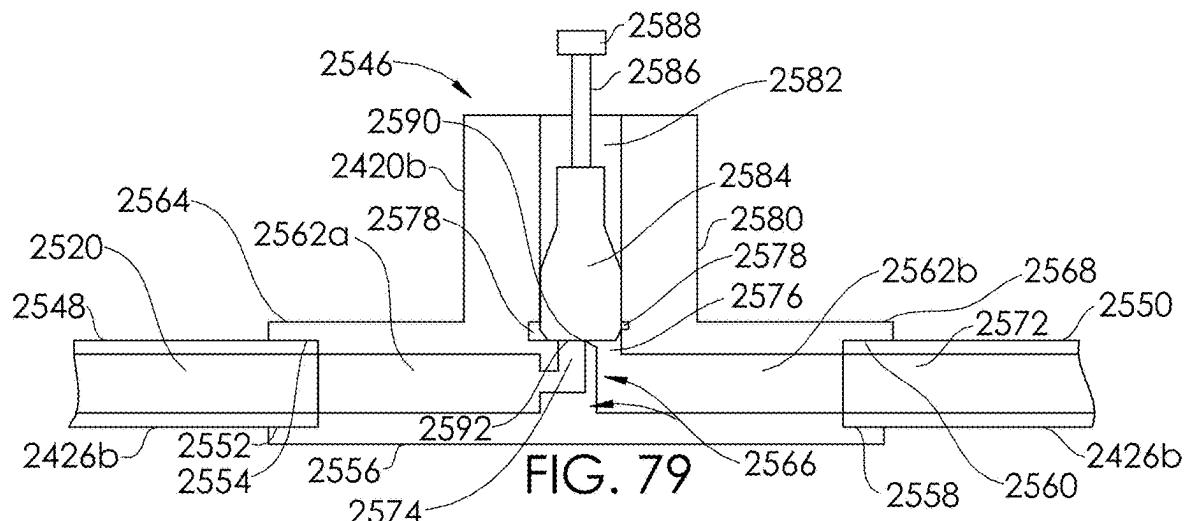
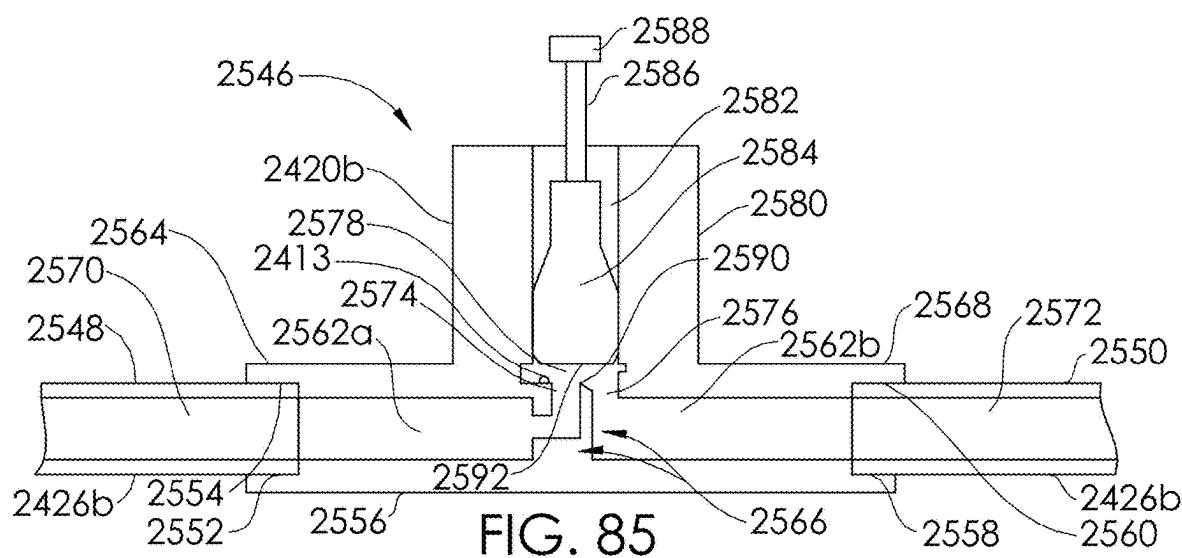
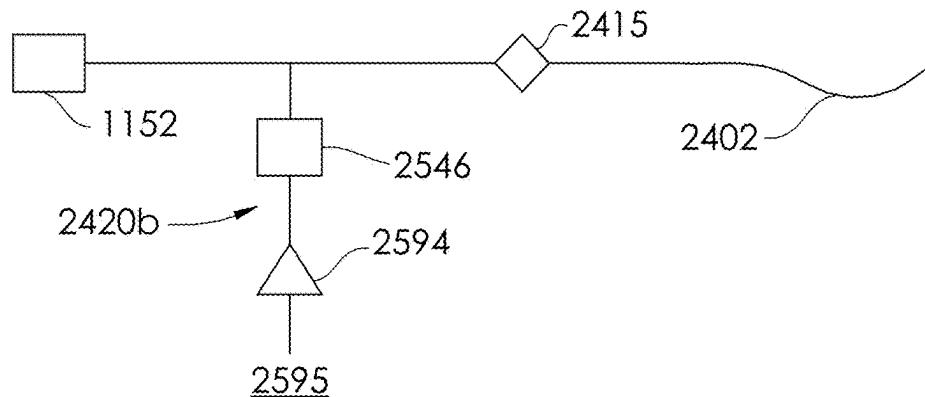
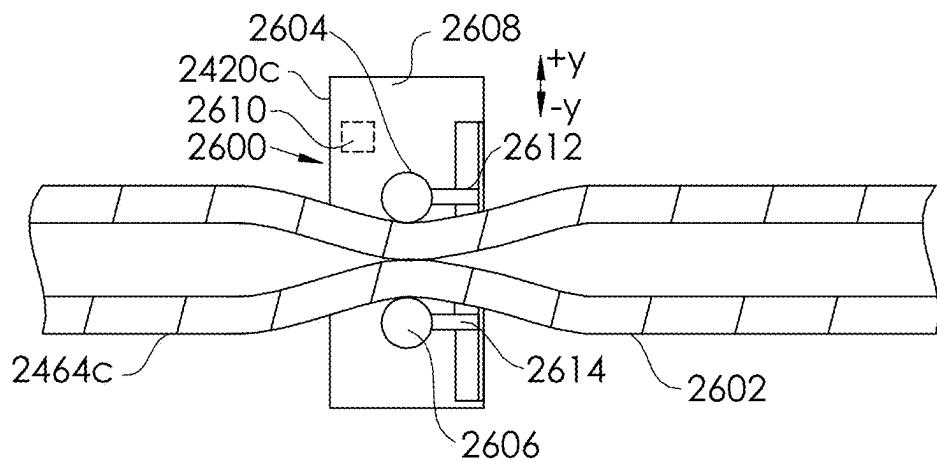
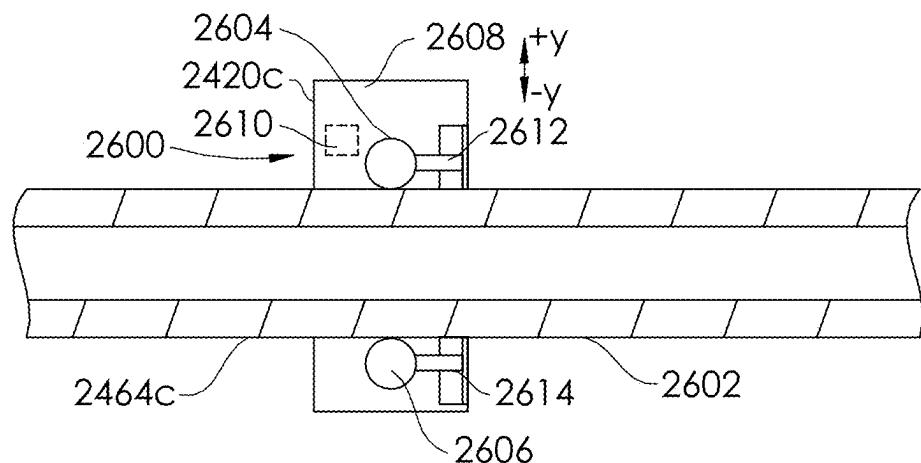


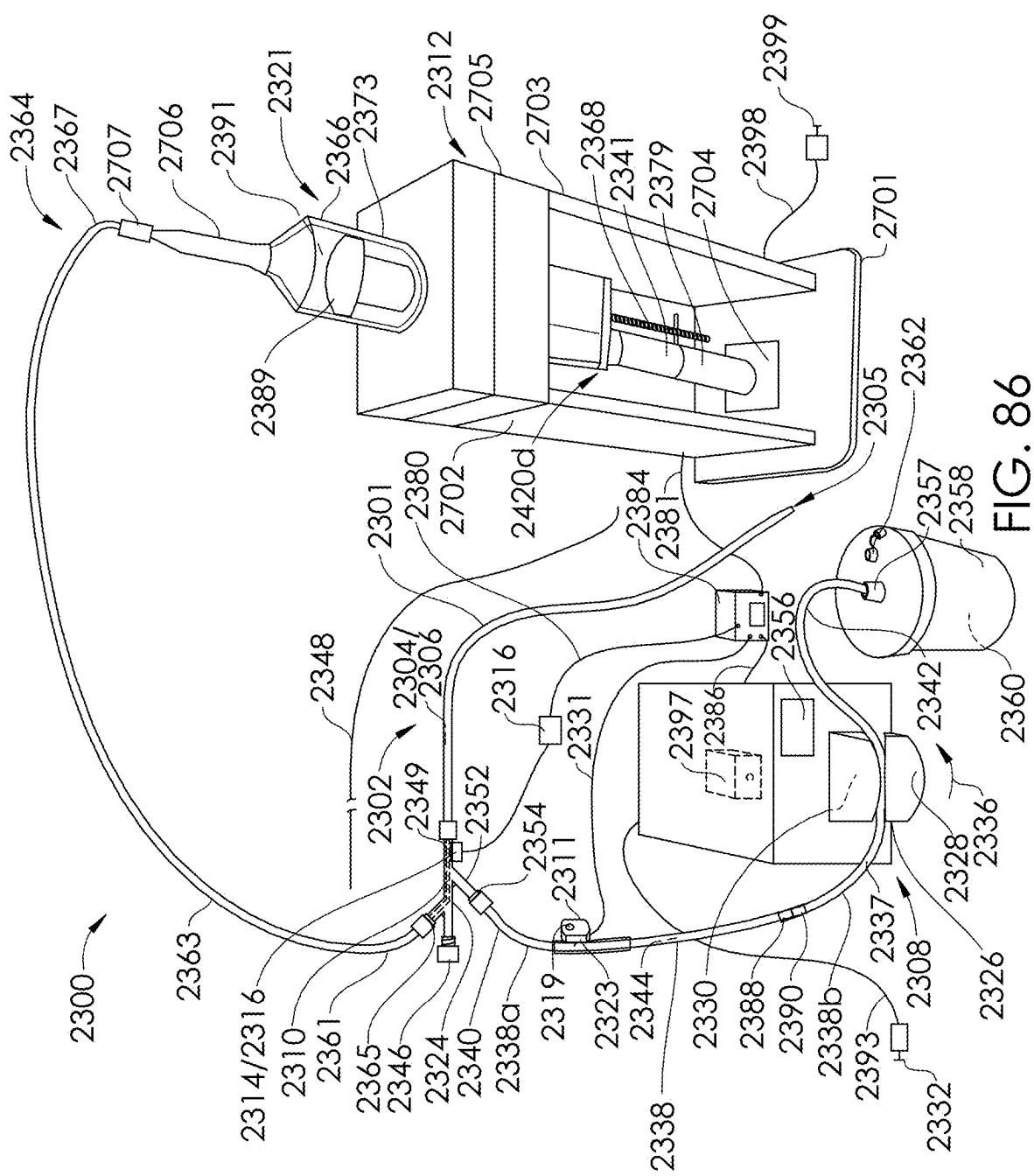
FIG. 76











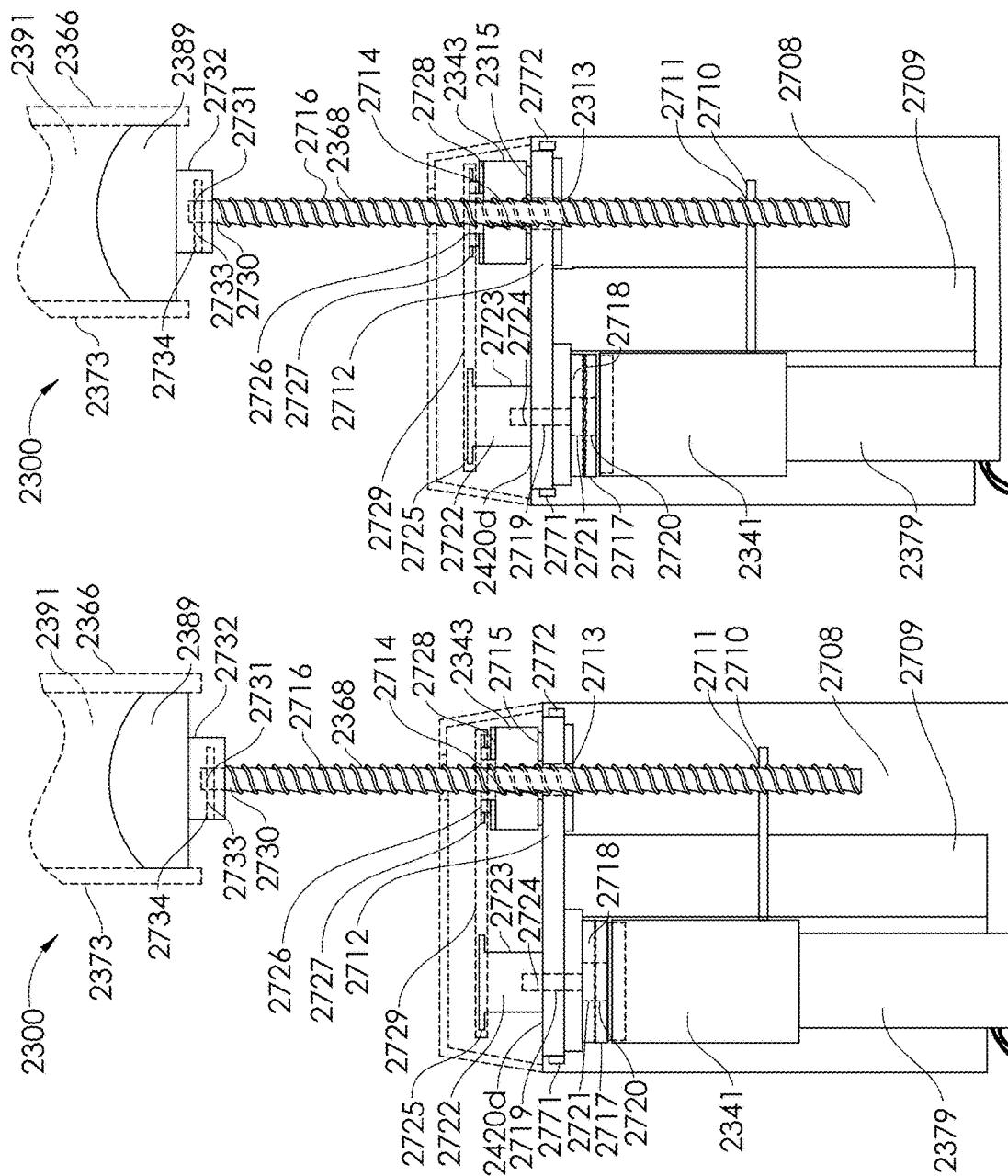
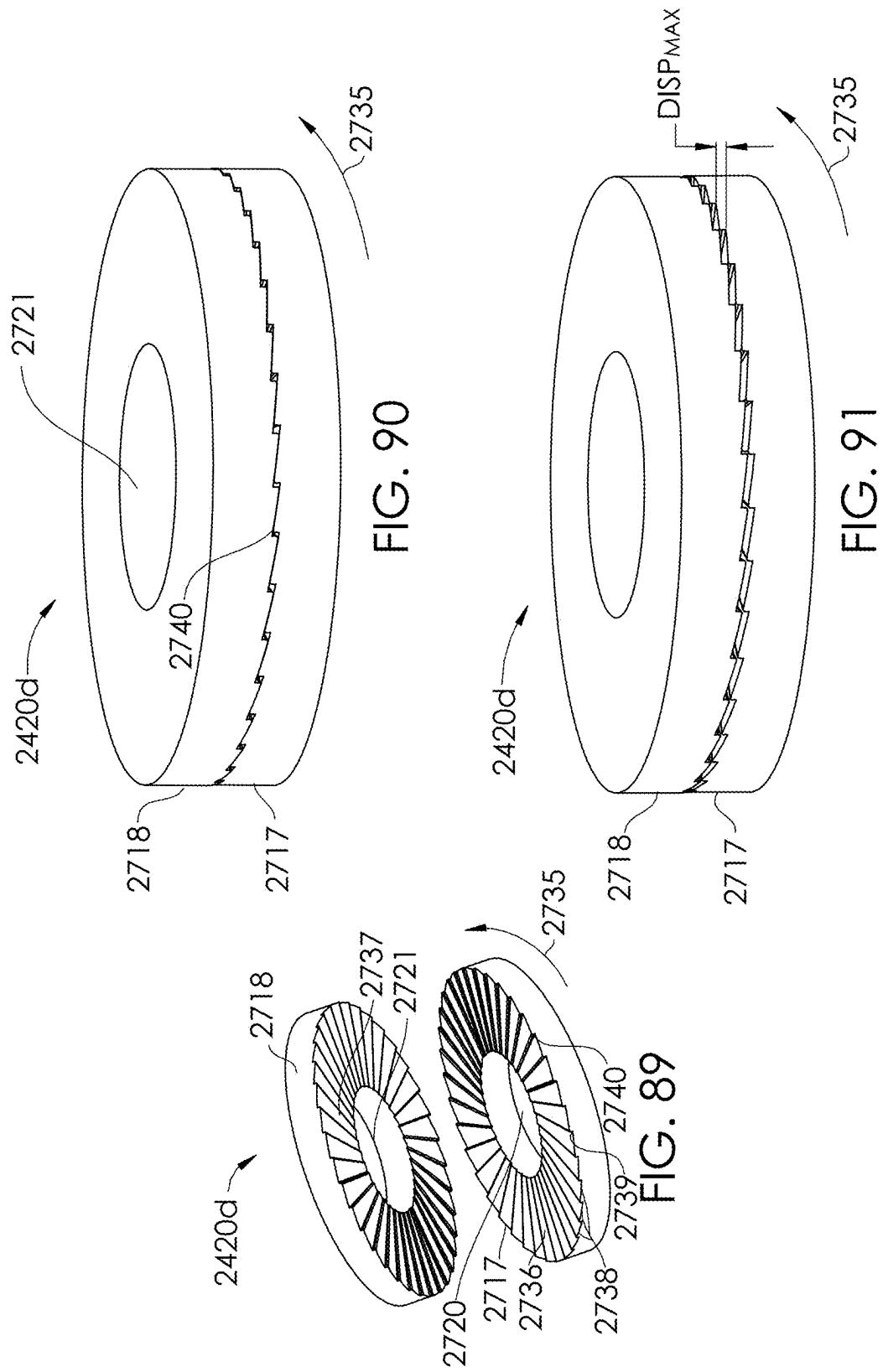


FIG. 88

FIG. 87



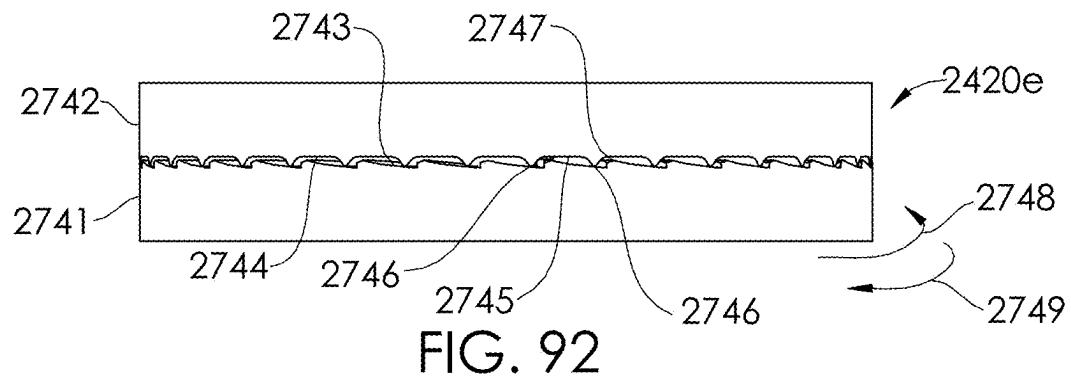


FIG. 92

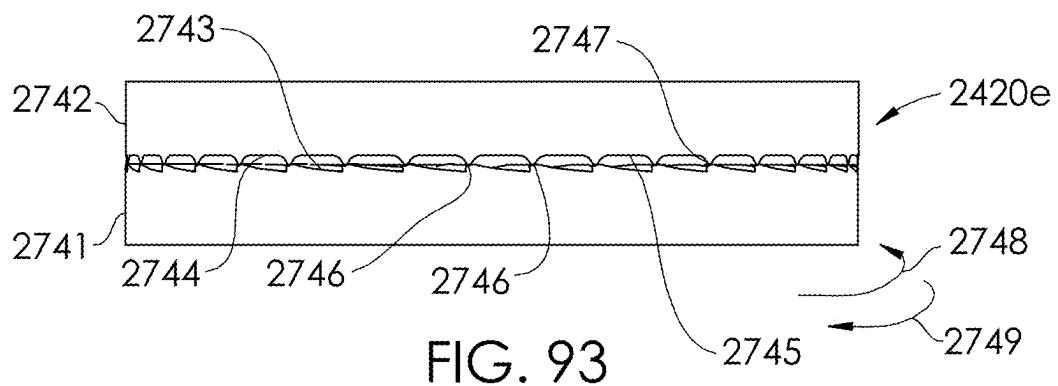


FIG. 93

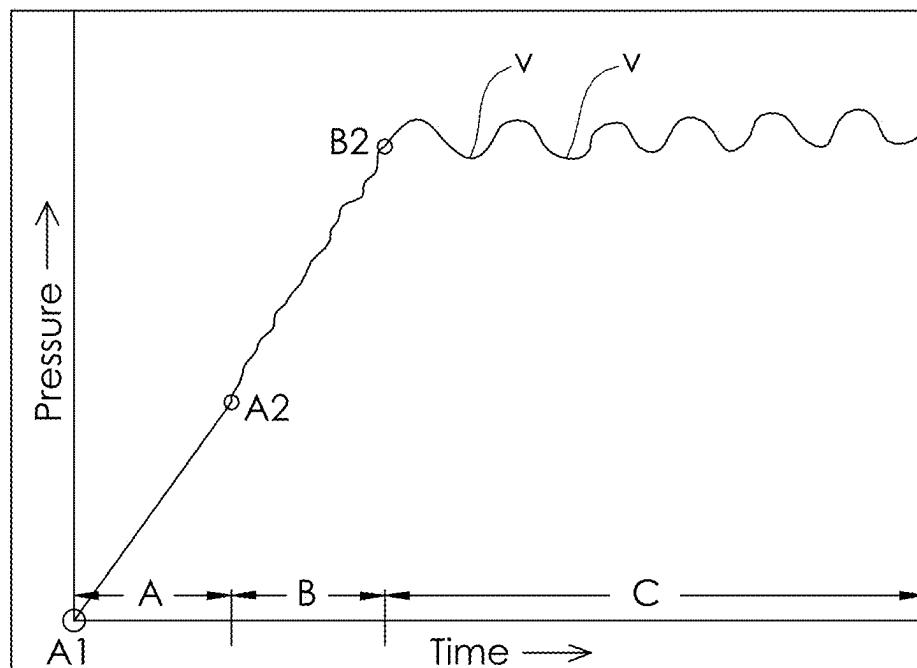


FIG. 94

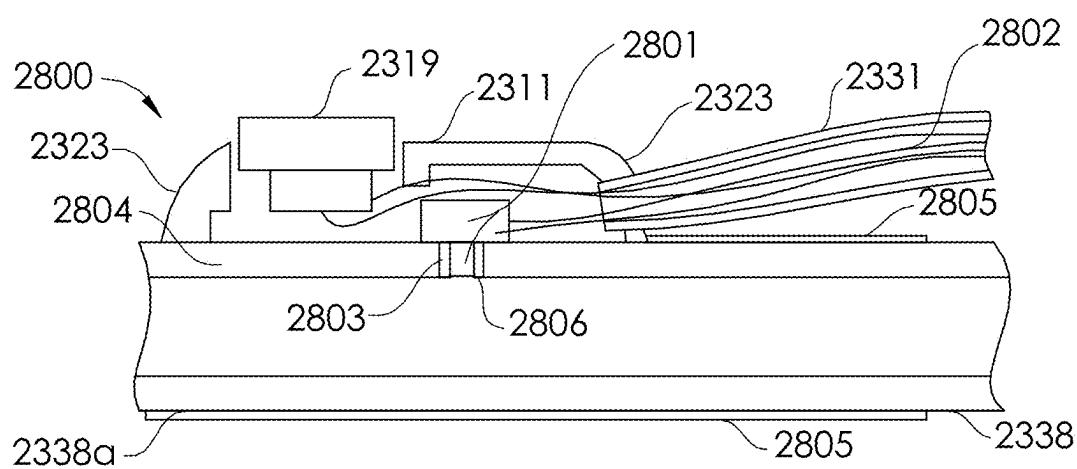


FIG. 95

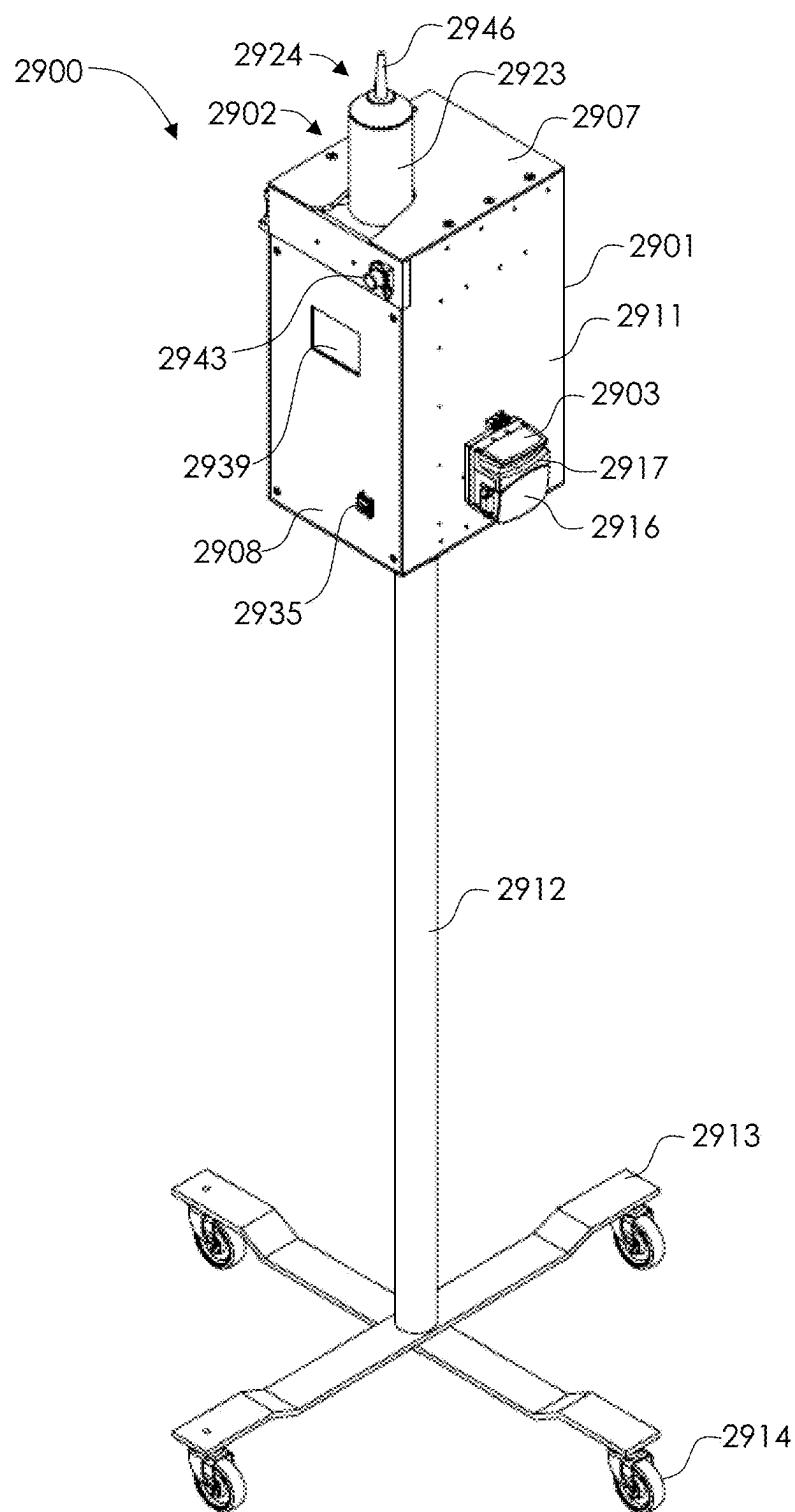


FIG. 96

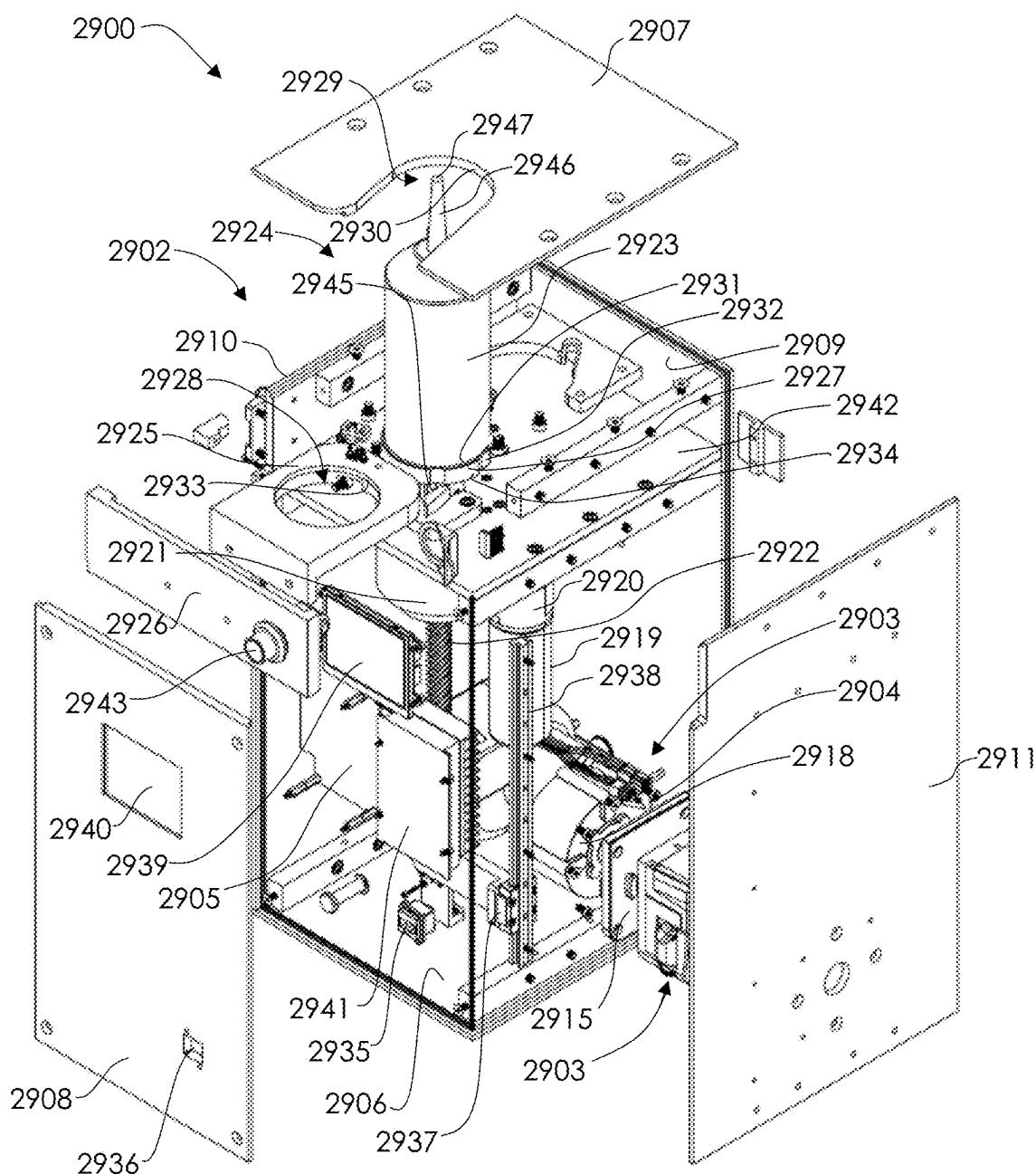


FIG. 97

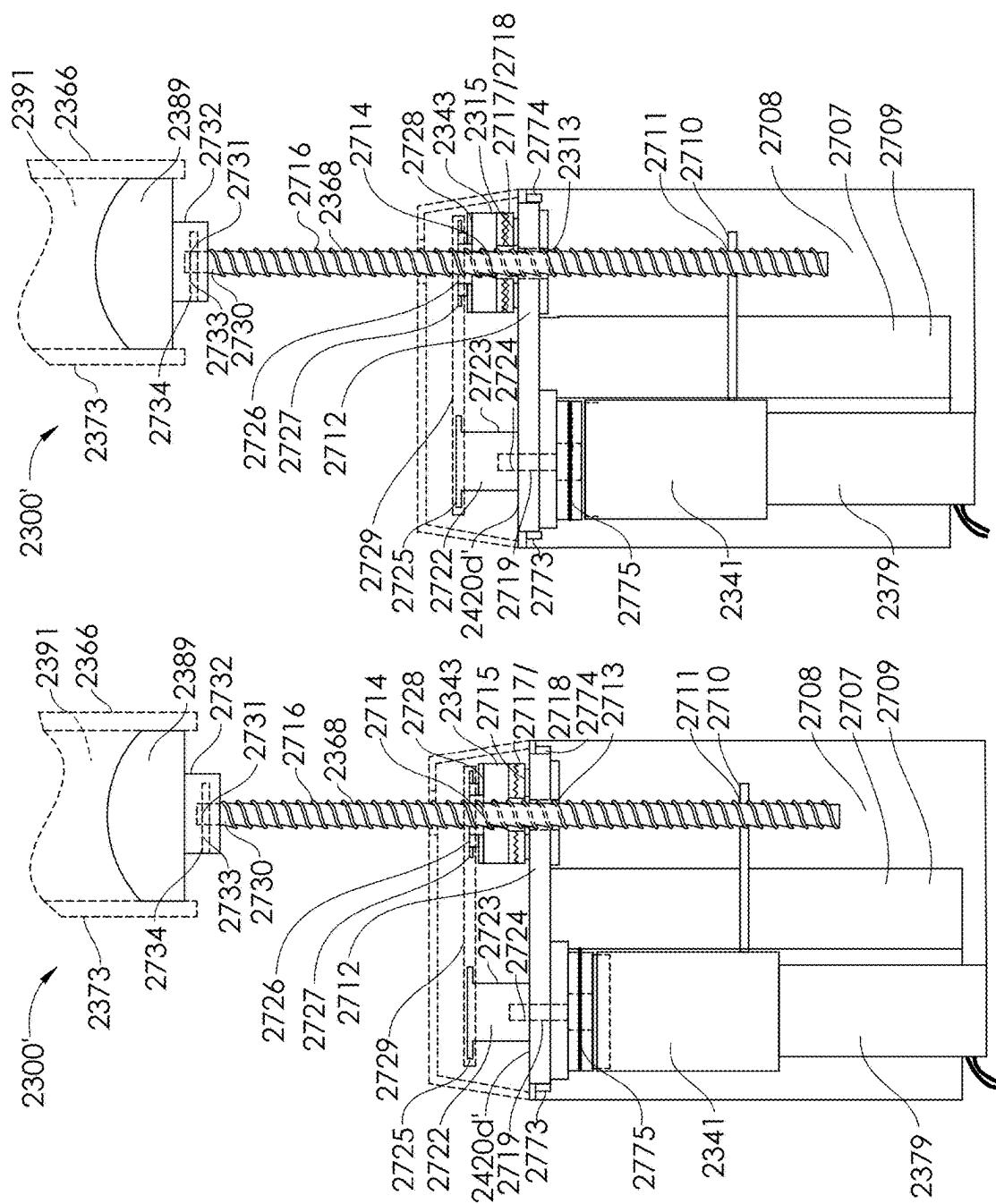


FIG. 99

EIG. 98

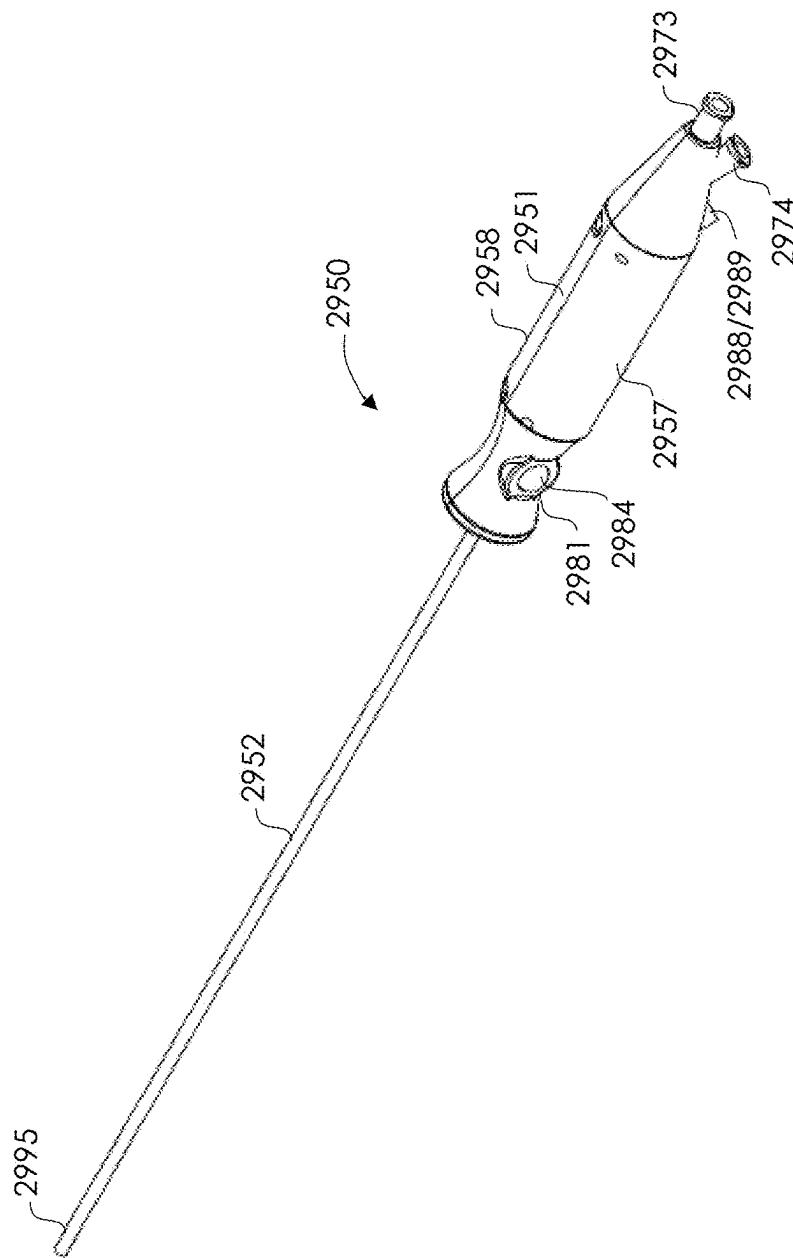


FIG. 100

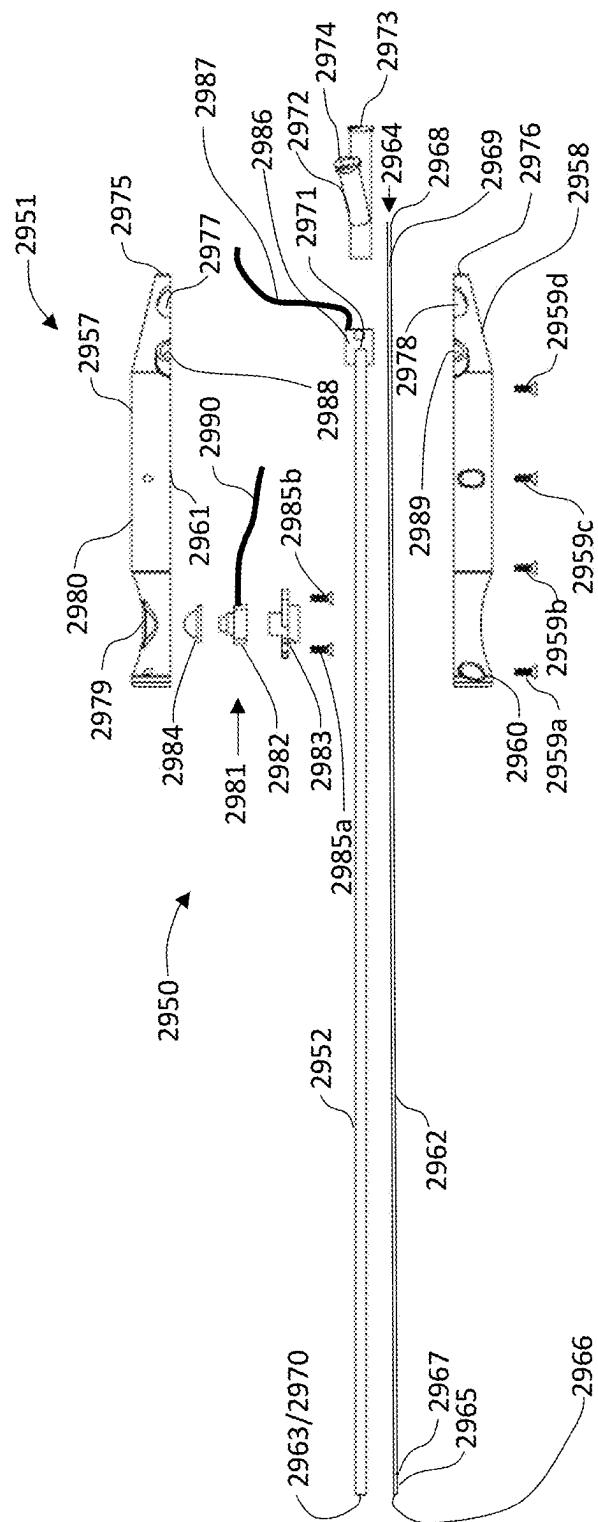


FIG. 101

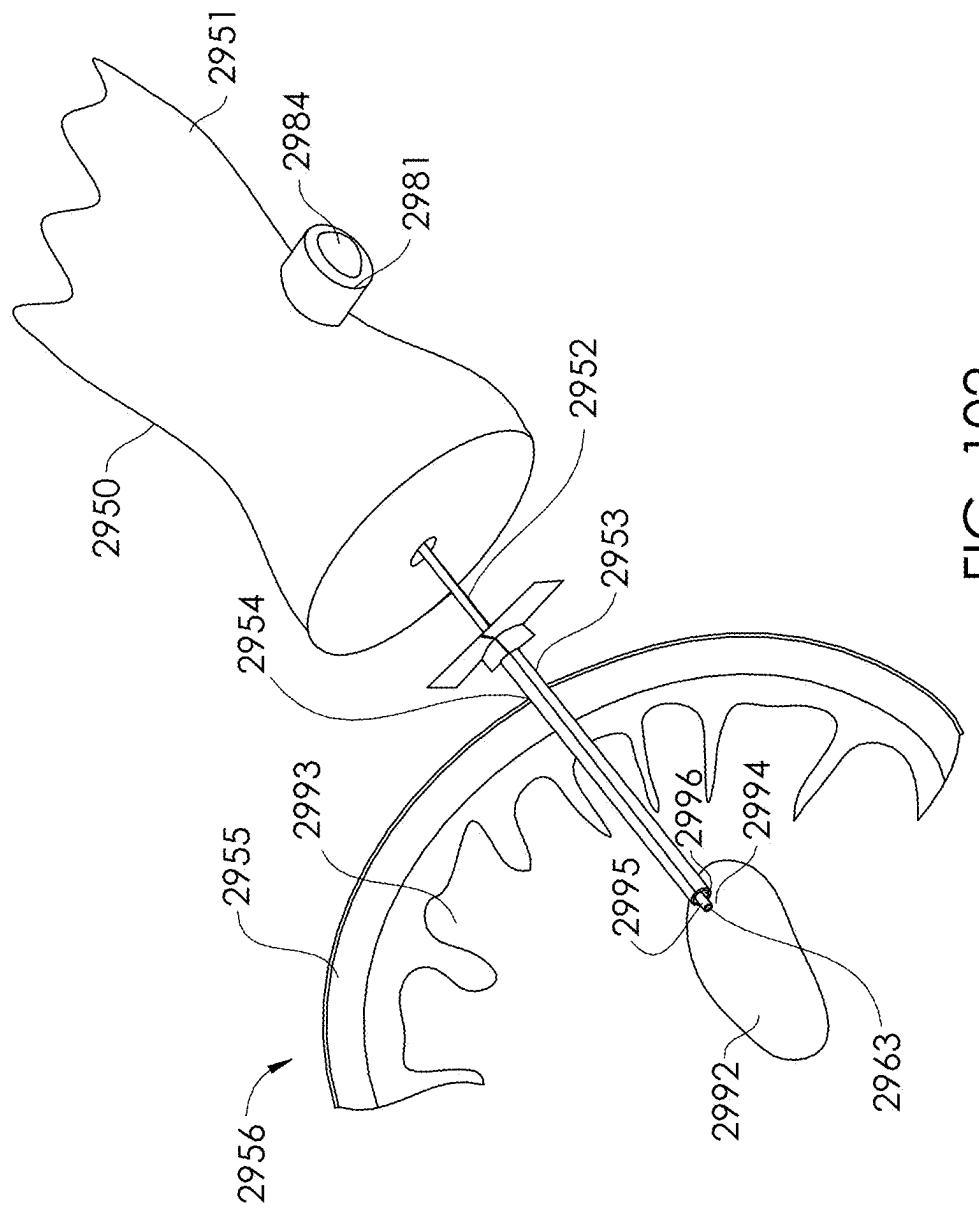


FIG. 102

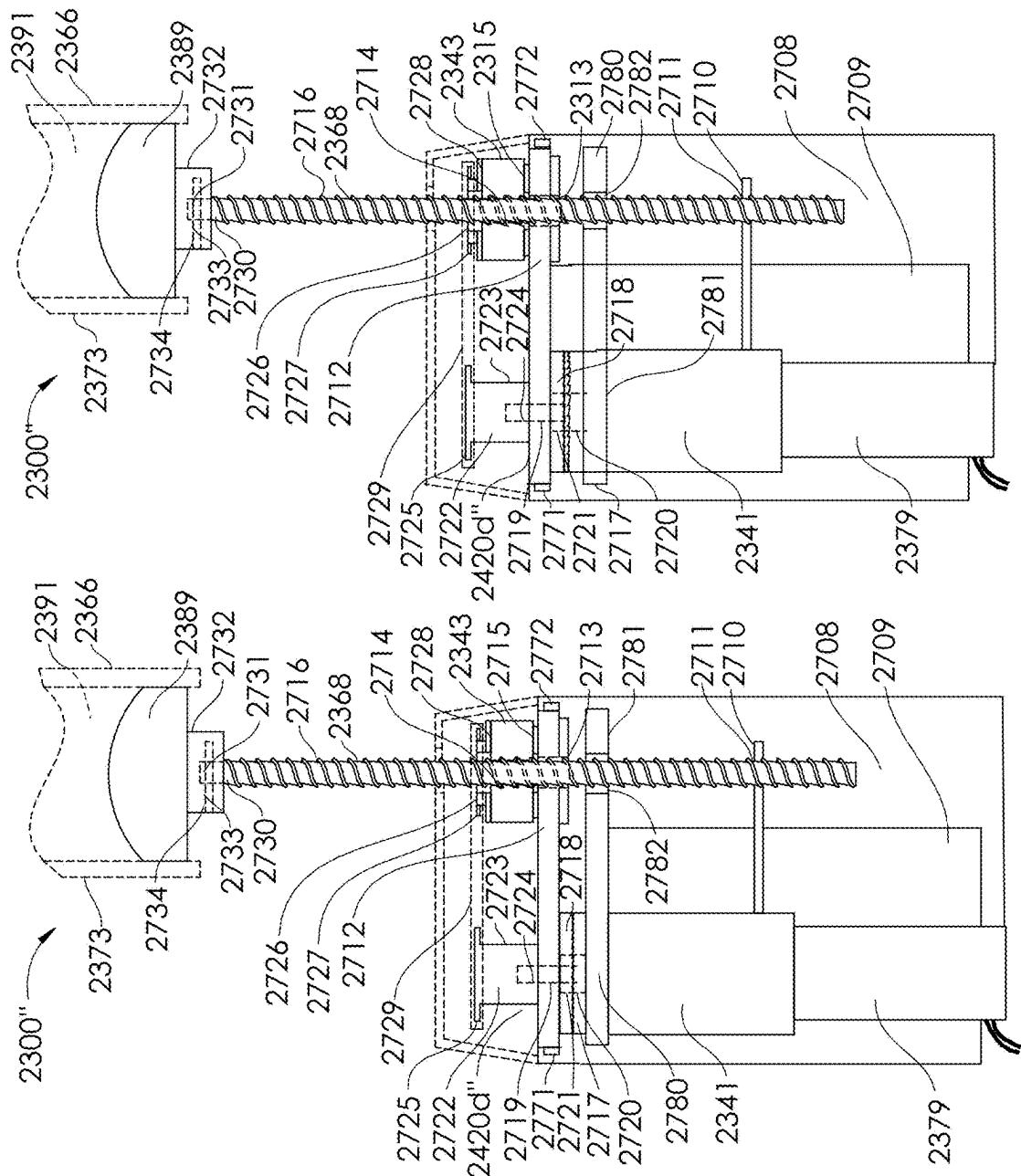


FIG. 104

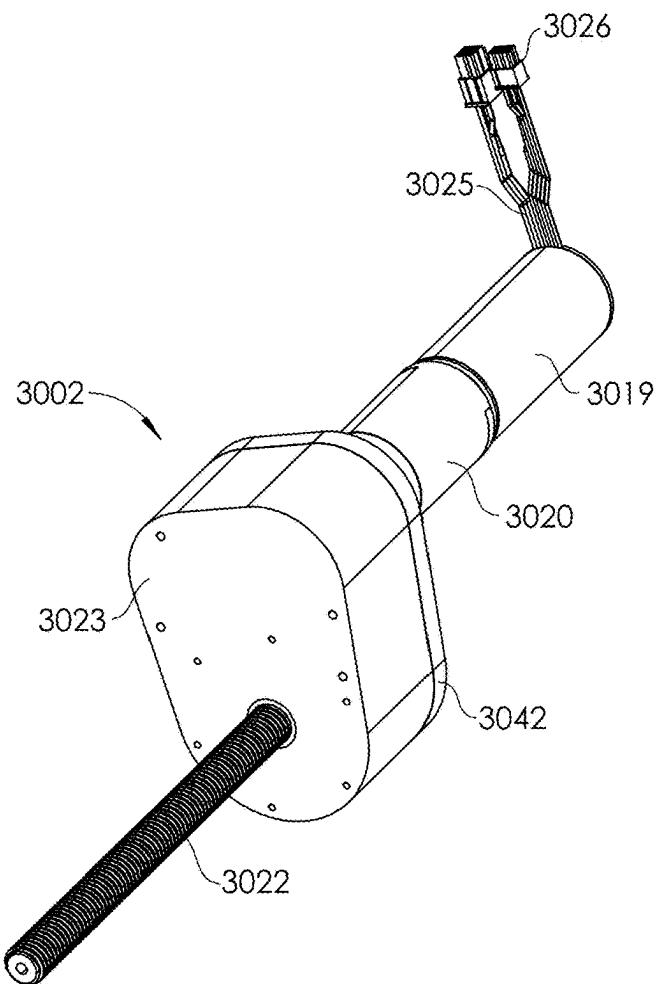


FIG. 105A

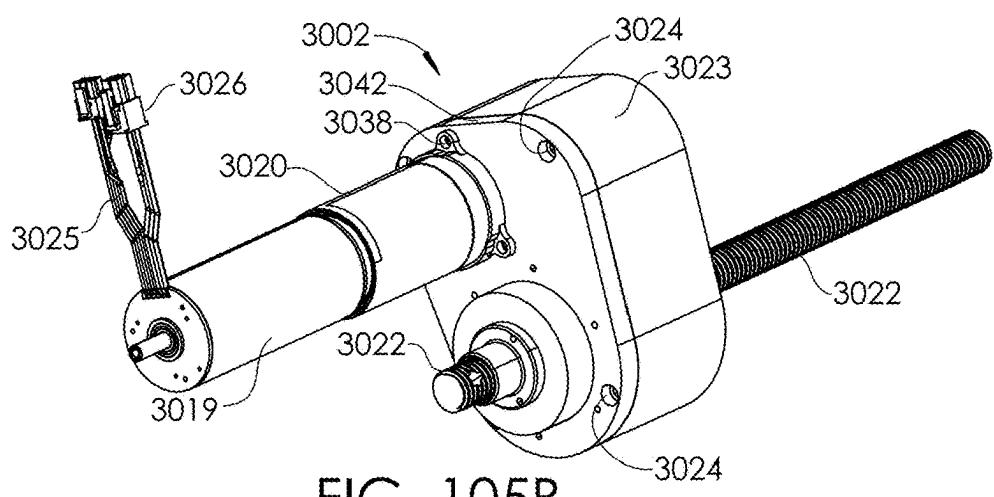


FIG. 105B

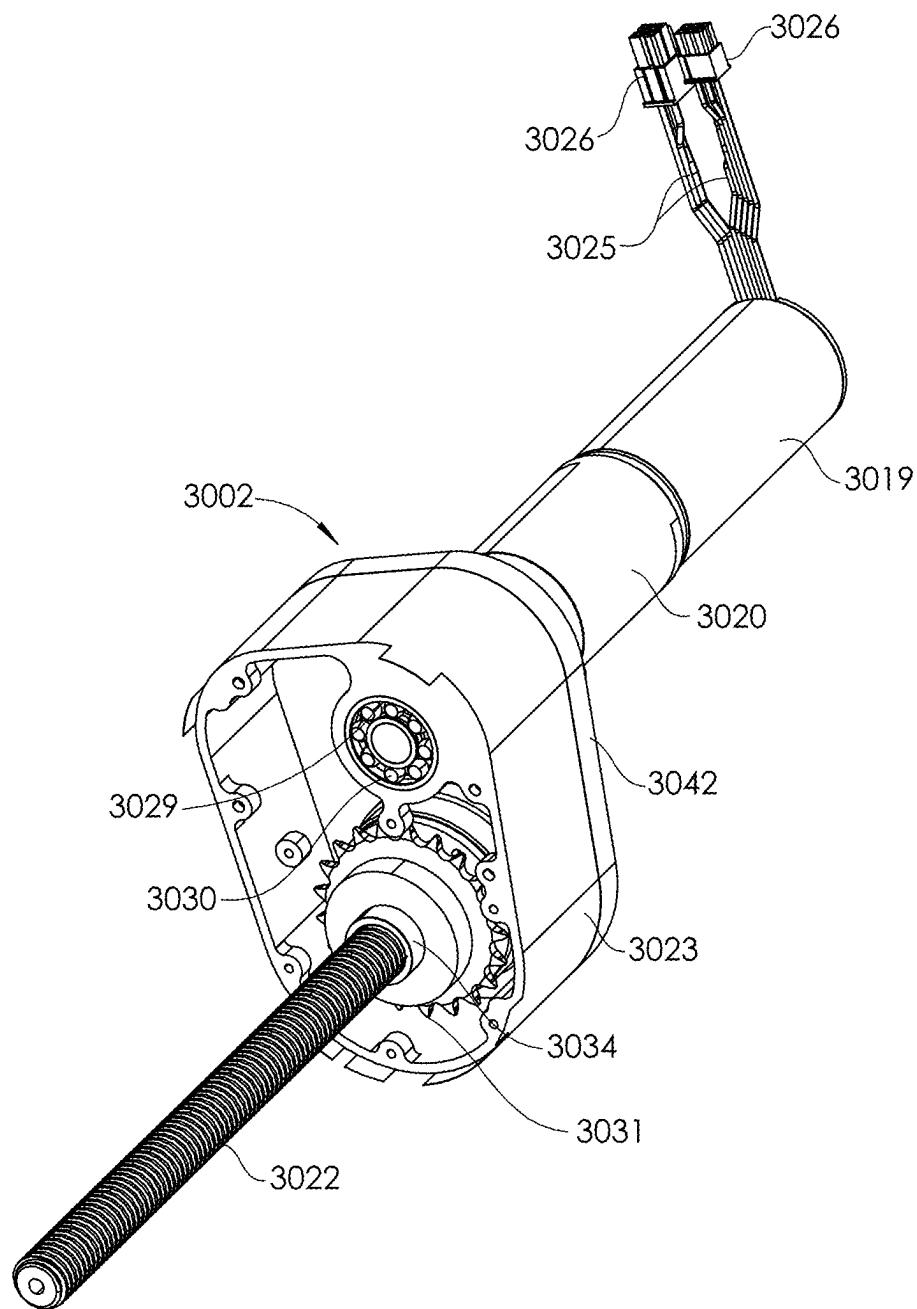


FIG. 106

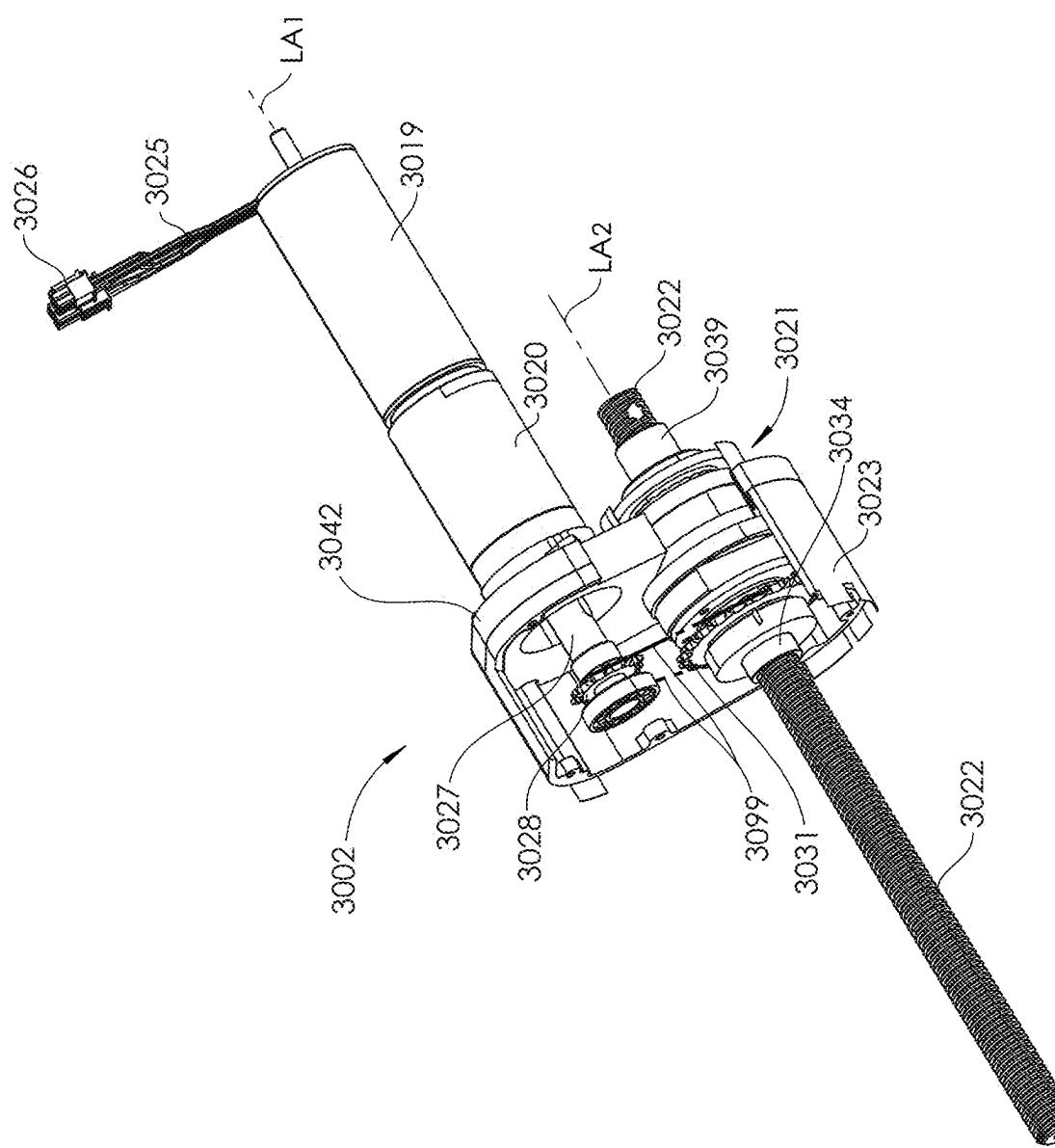


FIG. 107

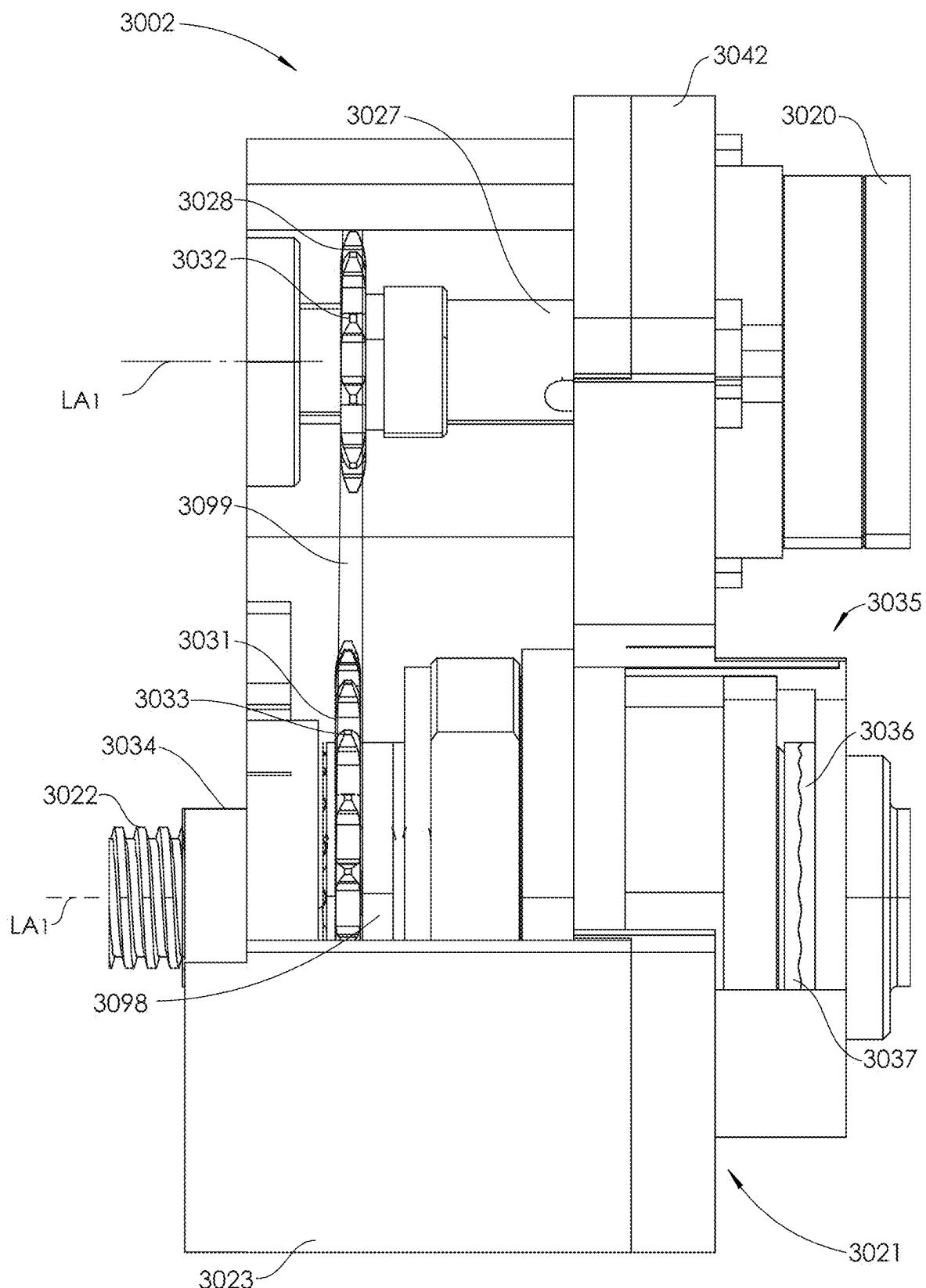


FIG. 108

## SYSTEMS AND METHODS FOR INJECTION AND ASPIRATION

### INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] This application is a Continuation-In-Part of U.S. patent application Ser. No. 18/755,567, filed on Jun. 26, 2024, which claims the benefit of priority to U.S. Provisional Patent Application No. 63/579,255, filed on Aug. 28, 2023, both of which are herein incorporated by reference in their entirety for all purposes. Priority is claimed pursuant to 35 U.S.C. § 120 and 35 U.S.C. § 119.

### BACKGROUND OF THE INVENTION

#### Field of the Invention

[0002] The field of the invention generally relates to an aspiration system for removing, by aspiration, undesired matter such as a thrombus from a fluid carrying cavity, duct, sinus, or lumen of the body, such as a blood vessel, including a vessel in the brain, or in any space in the body, whether intended to carry fluid or not.

### SUMMARY OF THE INVENTION

[0003] In one embodiment of the present disclosure, a system for catheter-based aspiration includes an aspiration catheter having a distal portion configured for insertion within a blood vessel of a subject, the aspiration catheter including an aspiration lumen having a distal opening at the distal portion of the aspiration catheter, an injection lumen having a distal end at the distal portion of the aspiration catheter, and an orifice located at or near the distal end of the injection lumen, the orifice configured to direct liquid into the aspiration lumen at or near the distal opening of the aspiration lumen; an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the aspiration lumen; and a mechanical oscillator coupled to the injector and configured to cause a pulsatile pressure of the liquid as it is injected through the injection lumen.

[0004] In another embodiment of the present disclosure, a method for catheter-based aspiration includes providing a catheter having a distal portion configured for insertion within a blood vessel of a subject, the catheter including a first lumen having a distal opening at the distal portion of the catheter, a second lumen having a distal end at the distal portion of the catheter, and an orifice located at or near the distal end of the second lumen, the orifice configured to direct liquid into the first lumen at or near the distal opening of the first lumen; and actuating an injector in a non-uniform manner to cause a pulsatile pressure of a liquid in the second lumen as the liquid is injected through the second lumen.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIG. 1 is a plan view of a system for aspiration according to an embodiment of the present disclosure.

[0006] FIG. 2A is a view of an aspiration monitoring system according to a first embodiment of the present disclosure.

[0007] FIG. 2B is a view of an aspiration monitoring system according to a second embodiment of the present disclosure.

[0008] FIG. 3 is a view of an aspiration monitoring system according to a third embodiment of the present disclosure.

[0009] FIG. 4A is a sectional view of an aspiration catheter in a blood vessel prior to contact with a thrombus.

[0010] FIG. 4B is a sectional view of an aspiration catheter in a blood vessel upon contact with a thrombus.

[0011] FIG. 4C is a sectional view of an aspiration catheter during a loss of aspiration.

[0012] FIG. 4D is a sectional view of thrombi being aspirated through an aspiration catheter.

[0013] FIG. 5A is a graphic representation of pressure vs. time for the condition of FIG. 4A.

[0014] FIG. 5B is a graphic representation of pressure vs. time for the condition of FIG. 4B.

[0015] FIG. 5C is a graphic representation of pressure vs. time for the condition of FIG. 4C.

[0016] FIG. 5D is a graphic representation of pressure vs. time for the condition of FIG. 4D.

[0017] FIG. 6 is a graphic representation of pressure and an output sound amplitude vs. time for an embodiment of an aspiration monitoring system.

[0018] FIG. 7 is a graphic representation of pressure and an output sound amplitude vs. time for an embodiment of an aspiration monitoring system.

[0019] FIG. 8 is a graphic representation of pressure and an output sound frequency vs. time for an embodiment of an aspiration monitoring system.

[0020] FIG. 9 is a graphic representation of pressure and an output of sound frequency vs. time for an embodiment of an aspiration monitoring system.

[0021] FIG. 10 is a plan view of a system for aspiration according to another embodiment of the present disclosure.

[0022] FIG. 11 is a plan view of a system for aspiration according to another embodiment of the present disclosure.

[0023] FIG. 12 is a detailed view of an aspiration monitoring system of the system for aspiration of FIG. 11.

[0024] FIG. 13 is a plan view of a system for aspiration according to another embodiment of the present disclosure.

[0025] FIG. 14 is a detailed view of an aspiration monitoring system of the system for aspiration of FIG. 13.

[0026] FIG. 15 is a diagrammatic view of a system for aspirating thrombus according to an embodiment of the present disclosure.

[0027] FIG. 16 is a diagrammatic view showing more detail of the proximal portion of the system for aspirating thrombus of FIG. 15.

[0028] FIG. 17 is a diagrammatic view of the distal end portion of the system for aspirating thrombus of FIG. 15.

[0029] FIG. 18 is a plan view of a portion of a multi-purpose system according to an embodiment of the present disclosure.

[0030] FIG. 19 is a perspective view of a proximal portion of the multi-purpose system of FIG. 18.

[0031] FIG. 20 is a plan view of a portion of a multi-purpose system according to an embodiment of the present disclosure.

[0032] FIG. 21 is a detail view of the distal end of a multi-purpose catheter of the multi-purpose system of FIG. 20.

[0033] FIG. 22 is a perspective view of a proximal portion of the multi-purpose system of FIG. 20.

[0034] FIG. 23 is a plan view of a proximal portion of the multi-purpose system of FIG. 20.

- [0035] FIG. 24 is a perspective view of a portion of the multi-purpose system of FIG. 20.
- [0036] FIG. 25 is a plan view of an aspiration catheter according to an embodiment of the present disclosure.
- [0037] FIG. 26 is a plan view of a tubing set according to an embodiment of the present disclosure.
- [0038] FIG. 27 is a plan view of a stopcock according to an embodiment of the present disclosure.
- [0039] FIG. 28 is a plan view of a stopcock according to an embodiment of the present disclosure.
- [0040] FIG. 29 is a plan view of a vacuum source according to an embodiment of the present disclosure.
- [0041] FIG. 30 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0042] FIG. 31 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0043] FIG. 32 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0044] FIG. 33 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0045] FIG. 34 is a partial sectional view of an embodiment of a saline injection aspiration (thrombectomy) catheter according to an embodiment of the present disclosure, with a guidewire in place.
- [0046] FIG. 35 is a plan view of the proximal end of a guiding catheter with an aspiration catheter placed therein.
- [0047] FIG. 36 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0048] FIG. 37 is a perspective view of a subject being reinjected with blood, according to an embodiment of the present disclosure.
- [0049] FIG. 38 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0050] FIG. 39 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0051] FIG. 40 is a perspective view of an ultrasonic sensor for use with an aspiration system, according to an embodiment of the present disclosure.
- [0052] FIG. 41 is a plan view of an aspiration system comprising a y-connector having the ultrasonic sensor of FIG. 40 placed therein.
- [0053] FIG. 42 is a perspective view of a console of the aspiration system of FIG. 41.
- [0054] FIG. 43 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0055] FIG. 44 is a detail view of the weight-based aspiration monitoring system of the system of FIG. 43.
- [0056] FIG. 45 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0057] FIG. 46 is a detail view of an alternative weight-based aspiration monitoring system of the system.
- [0058] FIG. 47 is a plan view of an aspiration system according to an embodiment of the present disclosure.
- [0059] FIG. 48 is a perspective view of an aspiration system, according to an embodiment of the present disclosure.
- [0060] FIG. 49 is a sectional view of the distal end of an aspiration catheter, according to an embodiment of the present disclosure.
- [0061] FIG. 50 is a sectional view of the distal end of an aspiration catheter, according to an embodiment of the present disclosure.
- [0062] FIG. 51 is a sectional view of the distal end of an aspiration catheter, according to an embodiment of the present disclosure.
- [0063] FIG. 52 is a sectional view of the distal end of an aspiration catheter, according to an embodiment of the present disclosure.
- [0064] FIG. 53 is a plan view of a microcatheter being tracked over a guidewire, in a first step.
- [0065] FIG. 54 is a plan view of the insertion of an insertable injection tube and cap being inserted into a microcatheter, in a second step according to an embodiment of the present disclosure.
- [0066] FIG. 55 is a plan view of the insertable injection tube and cap being advanced through a lumen of the microcatheter, in a third step.
- [0067] FIG. 56 is a plan view of the insertable injection tube and cap in a fully inserted position within the microcatheter, in a fourth step.
- [0068] FIG. 57 is a perspective cut-away view of a distal end of an insertable injection tube and cap with a spline inserted within a microcatheter, according to an embodiment of the present disclosure.
- [0069] FIG. 58 is a perspective view of the insertable injection tube and cap with spline of FIG. 57.
- [0070] FIG. 59 is a perspective cut-away view of a distal end of an insertable injection tube and cap with a spline inserted within a microcatheter, according to an embodiment of the present disclosure.
- [0071] FIGS. 60-63 illustrate a method for treating a patient using an aspiration catheter and system, according to an embodiment of the present disclosure.
- [0072] FIGS. 64-65 illustrate a method for treating a patient using an aspiration catheter and system, according to an embodiment of the present disclosure.
- [0073] FIGS. 66-69 illustrate a method for treating a patient using an aspiration catheter and system, according to an embodiment of the present disclosure.
- [0074] FIG. 70 is a sectional view of a translatable occluder of the aspiration system of FIGS. 66-69 in a first position, according to an embodiment of the present disclosure.
- [0075] FIG. 71 is a sectional view of the translatable occluder of the aspiration system of FIGS. 66-69 in a second position.
- [0076] FIG. 72 illustrates an optional blocking step in the method of FIGS. 66-69, according to an embodiment of the present disclosure.
- [0077] FIG. 73 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0078] FIG. 74 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0079] FIG. 75 is a perspective view of an aspiration system according to an embodiment of the present disclosure.
- [0080] FIG. 76 is a sectional view of an aspiration system according to an embodiment of the present disclosure.
- [0081] FIGS. 77-78 illustrate a first embodiment of a flow oscillator of the system of FIG. 76, according to an embodiment of the present disclosure.

[0082] FIGS. 79-81 illustrate a second embodiment of a flow oscillator of the system of FIG. 76, according to an embodiment of the present disclosure.

[0083] FIG. 82 is an alternative block diagram, according to an embodiment of the present disclosure.

[0084] FIGS. 83-84 illustrate a third embodiment of a flow oscillator of the system of FIG. 76, according to an embodiment of the present disclosure.

[0085] FIG. 85 is an alternative embodiment of the flow oscillator of FIGS. 79-81.

[0086] FIG. 86 is a perspective view of an aspiration system according to an embodiment of the present disclosure.

[0087] FIGS. 87-88 are elevation views of the aspiration system of FIG. 86.

[0088] FIG. 89 is an exploded view of first and second disks of a flow oscillator of the aspiration system of FIG. 86, according to a first embodiment of the present disclosure.

[0089] FIG. 90 is a perspective view of the first and second disks of the flow oscillator of FIG. 89 in a first relative rotational orientation.

[0090] FIG. 91 is a perspective view of the first and second disks of the flow oscillator of FIG. 89 in a second relative rotational orientation.

[0091] FIG. 92 is a side view of first and second disks of a flow oscillator of the aspiration system of FIG. 86, according to an alternative embodiment of the present disclosure, with the first and second disks in a first relative rotational orientation.

[0092] FIG. 93 is a side view of the first and second disks of the flow oscillator of FIG. 92 in a second relative rotational orientation.

[0093] FIG. 94 is a graphic representation of pressure vs. time of an aspiration system having a flow oscillator, according to an embodiment of the present disclosure.

[0094] FIG. 95 is a sectional view of a hand switch of the aspiration system of FIG. 86, according to an embodiment of the present disclosure.

[0095] FIG. 96 is a perspective view of an aspiration system according to an embodiment of the present disclosure.

[0096] FIG. 97 is an exploded view of the aspiration system of FIG. 96.

[0097] FIGS. 98-99 are elevation views of an alternative aspiration system, according to an embodiment of the present disclosure.

[0098] FIG. 100 is a perspective view of a surgical aspiration probe, according to an embodiment of the present disclosure.

[0099] FIG. 101 is an exploded view of the surgical aspiration probe of FIG. 100.

[0100] FIG. 102 is a perspective view of the surgical aspiration probe of FIG. 100 in use within the brain of a patient, according to an embodiment of the present disclosure.

[0101] FIGS. 103-104 are elevation views of an alternative aspiration system, according to an embodiment of the present disclosure.

[0102] FIG. 105A is a first perspective view of a high-pressure pump, according to an embodiment of the present disclosure.

[0103] FIG. 105B is a second perspective view of the high-pressure pump of FIG. 105A, according to an embodiment of the present disclosure.

[0104] FIG. 106 is a first cut-away perspective view of the high-pressure pump of FIG. 105A, according to an embodiment of the present disclosure.

[0105] FIG. 107 is a second cut-away perspective view of the high-pressure pump of FIG. 105A, according to an embodiment of the present disclosure.

[0106] FIG. 108 is a cut-away detailed view of the high-pressure pump of FIG. 105A.

#### DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0107] The present disclosure relates to aspiration catheter systems and monitoring, warning and communication systems for aspiration catheter systems, including aspiration systems for removing thrombus from the vasculature of patients. Such vasculature can include veins and arteries, including coronary arteries, carotid arteries, cerebral arteries, and other arteries of the head and neck. Clogging of aspiration catheters, for example by large pieces of thrombus, is a common concern for users. Techniques to avoid clogging/choking of material within the catheter often involve rapidly, aggressively advancing the aspiration catheter or gently plucking at edges of a thrombus to insure only small pieces or portions are introduced at a time, pieces which are small enough to not clog or occlude the aspiration lumen. When a device becomes clogged during use, the potential for inadvertent dislodgment of thrombus downstream increases; this is referred to as distal embolism. As aspiration procedures of this type are often used in highly technical emergent settings, early clog detection of the aspiration catheter for the user during aspiration can contribute to the success of the procedure and clinical outcome. Some sources have reported that up to 50% of aspiration catheters used get clogged during use.

[0108] The user may have difficulty determining whether there is a vacuum or negative pressure in the system or not. For example, the user may have difficulty determining whether the vacuum or negative pressure has been applied or not (e.g., the vacuum source has been turned on or off). Additionally, the user may have difficulty determining whether there has been a loss of vacuum in the system, for example because of the syringe (or other vacuum source) being full of fluid or because of a leak in the system. Blood is relatively opaque and can coat the wall of the syringe, thus making it difficult to determine when the syringe becomes full. This makes it difficult to determine whether sufficient vacuum or negative pressure is being applied to the aspiration catheter. The negative pressure gradient can change to an unacceptable level even before the syringe becomes full. Extension tubing or other tubing can also cause a loss in vacuum or negative pressure in the system. Certain tubing kinks can be difficult for a user to see or identify. It is also difficult to determine whether there is an air leak in the system, which can be another cause for a loss of vacuum or negative pressure even before the syringe becomes full of the aspirated fluid.

[0109] During the aspiration of thrombus with an aspiration catheter, it is difficult to identify when thrombus is actively being aspirated, or when only blood is being aspirated. Typically, it is desired to not aspirate sizable quantities of normal blood from blood vessels, because of the importance of maintaining normal blood volume and blood pressure. However, when tracking the tip of an aspiration catheter in proximity to a thrombus, it is difficult to know

whether the aspiration catheter has actively engaged a thrombus, whether it has aspirated at least a portion of the thrombus, or whether it is not engaged with the thrombus, and is only aspirating blood. Though some aspiration catheters, such as those used in the peripheral blood vessels or in an arterio-venous fistula, can be around 50 cm or even less, the tip of an aspiration catheter can in same cases be more than 90 cm from the hands of the user, or as much as 135 cm from the hands of the user, or in some cases as much as 150 cm, and the particular status of aspiration capability at the tip of the catheter is often not known by the user. A user can thus be essentially plunging a catheter blindly without significant, usable sensory feedback. The catheter can have an outer diameter up to or even greater than 6 French, and can be as high as 10 French or greater. The increased catheter outer diameter can cause some concern of potential trauma inside a blood vessel. The use of aspiration catheters can therefore be inefficient, and cause more blood removal than desired, causing a user to minimize the length of the therapy and in severe cases necessitating blood transfusion. An increased volume of normal blood being aspirated also means that the vacuum source (e.g. syringe) will fill in a shorter amount of time, thus requiring more frequent replacement of the vacuum source. Distal embolism can occur if the negative pressure gradient is not sufficient, and yet the user is not aware.

[0110] In some cases, a syringe that is completely or mostly full or blood and/or thrombus can continue to be used, though in this state, there is not sufficient pressure to effectively aspirate thrombus or unwanted material, thus causing inefficient use of time, and lengthening the procedure. In some cases, the user may not realize the plunger of the syringe has mistakenly not been pulled back (to evacuate the syringe). In some cases, the syringe itself can be defective, and a sufficient negative pressure may not be achieved, without the user being aware. In some cases, kinked tubing, lines, or catheters can go unnoticed, because of bad visibility in a procedural laboratory, or simply from the extent of concurrent activities being performed. In many cases, the user's eyes are oriented or focused on a monitor, for example a fluoroscopic monitor or other imaging monitor, or a monitor with patient vital data. Though the user may be able to view flow through transparent or partially transparent lumens (such as extension tubing), in dim lighting with intermittent viewing, it is difficult for the user's mind to process flow of an opaque liquid (such as blood/thrombus). Even in good lighting with a focused eye, the movement of fluid through extension tubing may not present an accurate picture of the aspiration status, as the visual flow effect can be delayed in relation to the applied vacuum or negative pressure. More than one medical device personnel can be sharing sensory information with each other to attempt to build a current status in each other's minds of the aspiration procedure. When a user relies on another's interpretation, especially when either are multitasking, a false sense of the status may occur. A syringe attached to the aspiration catheter can cause kinking, for example, if placed on an uneven surface. The distal opening in an aspiration lumen of an aspiration catheter can be prone to aspirating directly against the wall of a blood vessel, thus being temporarily stuck against the vessel wall, and stopping flow throughout the aspiration lumen. In some cases, a negative pressure gradient that is too large can be accidentally or inappropriately applied to the aspiration lumen of the aspiration

catheter, limiting effectiveness (for example, if it causes the walls surrounding the aspiration lumen to collapse and thus, cut off the significantly decrease the flow through the aspiration lumen). The syringes which are sometimes used as a vacuum source to connect to an aspiration lumen of an aspiration catheter can malfunction, and not be fully actuated/evacuated. But, even when the syringe is functioning correctly, it will tend to fill up at difficult to predict moments, and thus commonly have periods with no applied negative pressure gradient. In the cases wherein a portion of clot/thrombus is being aspirated through the aspiration lumen, a significant pressure drop can occur at the current position of the thrombus, and thus, a sufficient negative pressure can only exist from the proximal end of the aspiration lumen and distally up to the point of the thrombus. Thus, an insufficient negative pressure can exist, causing insufficient aspiration at the distal end of the aspiration lumen, e.g., at the distal end of the aspiration catheter. The same situation can occur if there is an actual clog at some intermediate point within the aspiration lumen. In either of these conditions, because of the insufficient aspiration at the distal end of the aspiration lumen, there can be a risk of thrombus or emboli being sent distally in the vasculature, which can cause occlusion, stroke, pulmonary embolism, or other disorders, depending upon the location of the intervention or procedure being performed. With current apparatus and techniques, these situations are very difficult to detect when they occur. It has been estimated that in as many as 50% of thrombus aspiration procedures, some sort of failure occurs.

[0111] An aspiration system 2 is illustrated in FIG. 1 and is configured to allow real time monitoring of catheter aspiration. The aspiration system 2 comprises an aspiration catheter 4, a vacuum source 6, a valve 8, extension tubing 10, and an aspiration monitoring system 48 including an in-line pressure transducer 12. The aspiration catheter 4 has a proximal end 14 and a distal end 16 and an aspiration lumen 18 extending from the proximal end 14 to the distal end 16. The aspiration lumen 18 can be sized for aspiration of thrombus, and in some embodiments can have an inner diameter of between about 0.38 millimeter (0.015 inches) and about 2.54 millimeters (0.100 inches). The aspiration catheter 4 includes a hub 20 at its proximal end which can include a female luer connector 22. The aspiration lumen 18 at the distal end 16 of the aspiration catheter 4 can include an angled orifice 24, which aids in the tracking through tortuous or occluded vasculature. In some embodiments, a guidewire lumen 26 is coupled to the distal end 16 of the aspiration catheter 4, and is configured to track over a guidewire 28. The vacuum source 6 can comprise a syringe, and can be sized between 5 ml and 100 ml, or between 20 ml and 60. The vacuum source 6 can comprise a VacLok® syringe, made by Merit Medical, South Jordan, Utah. The vacuum source 6 can include a barrel 30 and plunger 32, with a lock 34 which is configured to retain the plunger 32 in position in relation to the barrel 30, for example, when the plunger 32 is pulled back in direction D to create a negative pressure (vacuum) inside the barrel 30. In some embodiments, the vacuum source 6 can comprise any other type of evolvable reservoir, or can comprise a vacuum pump. The vacuum source 6 is connected to the aspiration lumen 18 of the aspiration catheter 4 via the extension tubing 10 and the valve 8. In some embodiments, the vacuum source 6 can be connected directly to the aspiration lumen 18 of the aspiration catheter 4. Male luer connectors 36 and female luer

connectors 38 are indicated in FIG. 1. The valve 8 can be a standard two-way stopcock, as illustrated.

[0112] The pressure transducer 12 of the aspiration monitoring system 48 is configured to be fluidly coupled between the vacuum source 6 and the aspiration catheter 4. In FIG. 2A, the aspiration monitoring system 48 is illustrated as a self-contained device of a first embodiment. The pressure transducer 12 comprises a housing 40 having a cavity 42 extending between a first port 44 and a second port 46. In some embodiments, the first port 44 comprises a female luer and the second port 46 comprises a male luer. In some embodiments, the first port 44 comprises a female luer lock and the second port 46 comprises a male luer lock, each of which is attachable to and detachable from a corresponding luer lock of the opposite gender. The first port 44 is configured to be coupled to the vacuum source 6, either directly, or with the valve 8 and/or extension tubing 10 connected in between. The second port 46 is configured to be coupled to the aspiration lumen 18 of the aspiration catheter 4, for example, by coupling the second port 46 directly or indirectly to the hub 20 of the aspiration catheter 4. When the aspiration system 2 is used to aspirate body fluids and/or materials, for example blood and/or thrombus, the body fluids and/or materials are aspirated through the aspiration lumen 18 of the aspiration catheter from the angled orifice 24 at the distal end 16 to the female luer connector 22 at the proximal end 14, then pass through the second port 46 of the pressure transducer 12 first, through the cavity 42, and then through the first port 44. Depending on the amount of vacuum or negative pressure applied by the vacuum source 6, and the amount of flow resistance and resulting pressure drop along the aspiration system 2, the pressure within the cavity 42 will vary. For example, a more viscous fluid like blood, or a fluid having solid, semi-solid, or gel-like particles or portions, will cause more flow resistance through the relatively small aspiration lumen 18 of the aspiration catheter 4 than would water or normal saline solution. Thus, the pressure within the cavity 42 of the pressure transducer 12 will decrease (the negative pressure gradient will increase) as the flow resistance in the aspiration lumen 18 increases.

[0113] For definition purposes, when speaking of the amount of "vacuum," a pressure of, for example, -15,000 pascal (-2.18 pounds per square inch, or psi) is a "larger vacuum" than -10,000 pascal (-1.45 psi). Actually, a true vacuum (-101,325 pascal or -14.7 psi at sea level), where no molecules are present within the volume is extremely difficult. Additionally, -15,000 pascal is a "lower pressure" than -10,000 pascal. Furthermore, -15,000 pascal has a larger "absolute vacuum pressure" than does -10,000 pascal, because the absolute value of -15,000 is larger than the absolute value of -10,000. In FIG. 2A, a vacuum sensor 50 is disposed within the cavity 42 of the housing 40 and is in fluid communication with fluid that passes through the cavity 42. The vacuum sensor 50 can be a standard pressure sensor or transducer, including a pressure sensor designed primarily for measuring positive pressure. It can use any type of pressure sensing technology known in the art, including MEMS Technology. In some embodiments, the vacuum sensor 50 is configured for highest accuracy and/or precision within the range of pressures between about 0 pascal to about-101,325 pascal (-14.70 psi), or between about-45,000 pascal (-6.53 psi) and about-90,000 pascal (-13.05 psi), or between about-83,737 pascal (-12 psi) and

about-96,527 pascal (-14 psi). In some embodiments, the power requirement for the vacuum sensor can range from 2.5 volts DC to 10 volts DC. In some embodiments, the vacuum sensor 50 can be an analog gauge with an output voltage. In the self-contained embodiment of the FIG. 2A, the vacuum sensor 50 is powered by one or more battery 52. Based on the power requirements of the vacuum sensor 50, and the power requirements of other components of the aspiration monitoring system 48 described herein, in some embodiments the one or more battery 52 can range between 1.5 volts and nine volts. Also contained within the housing is a measurement device 54, which in some embodiments can comprise a microprocessor. The measurement device 54 is coupled to the vacuum sensor 50 and receives signals from the vacuum sensor 50 indicative of real time measured pressure. In some embodiments, the measurement device 54 includes a memory module 56 in which information is stored that can be used by the measurement device 54, for example, in calculations. Information can include, for example, an array of one or more pressure values. In some embodiments, the array of one or more pressure values can be correlated with one or more different corresponding system models or catheter models. The vacuum sensor 50 can be used in some cases for detecting the presence or amount of vacuum or negative pressure alone, for the purpose of monitoring whether the vacuum source 6 (e.g., syringe) is significantly full, and thus needs to be changed. The vacuum sensor 50 can be used in some cases for detecting whether there is a vacuum or negative pressure in the system or not. For example, whether the vacuum or negative pressure has been applied or not (e.g., the vacuum source has been turned on or off).

[0114] One or more communication devices 58a, 58b, 58c are included within the aspiration monitoring system 48 and are coupled to the measurement device 54. Each of the one or more communication devices 58a-c are configured to generate a type of alert comprising an alert signal 60a-c, in response at least in part to activity and output of the measurement device 54. In some embodiments, the communication device 58a can include one or more LEDs (light emitting diodes) configured to generate a visible alert via a visible alert signal 60a, such as light that is continuously illuminated, or is illuminated in a blinking pattern. In some embodiments, the LEDs can be oriented on multiple sides of the communication device 58a, so that they can be easily seen from a variety of different locations. In some embodiments, lights other than LEDs can be used. Light pipes or other lighting conduits can also be incorporated in embodiments, to further place visual indicators at multiple locations and/or orientations. In some embodiments, the communication device 58b can include one or more vibration generators configured to generate a tactile alert via a tactile alert signal 60b, which can include, but is not limited to, vibration or heat. In some embodiments, the vibration device can be similar to a video game controller. In some embodiments, the vibration generator can comprise a piezoelectric device which is configured to vibrate when a voltage is applied. In some embodiments, the communication device 58c can include one or more sound generating devices configured to generate an audible alert via an audible alert signal 60c, such as a continuous noise, or a repeating noise. The communication device 58c in some embodiments can comprise a loudspeaker for generation of any variety of sounds, at any variety of frequencies (Hz) or sound pressures (dB) within

the human audible range and/or human tolerance range. The communication device **58c** can even be configured to generate sounds that are outside the human audible range in embodiments wherein the signal is intended to be felt as a vibration or other tactile sensation, instead of an audible sensation. In some embodiments, the sound generating device can comprise a buzzer which is configured to sound one or more audible pitches when a voltage is applied. In some embodiments a piezoelectric device, such as that described in relation to the communication device **58b** can also serve as a sound generating device, included as communication device **58c**. The alert signal **60a-c** can at times serve as a “wake up” alarm for the user, in cases where the user has become too focused on other factors during the procedure.

**[0115]** A user of an aspiration system **2** can desire to be notified of several conditions which can occur during use of the aspiration system **2**. These potential conditions include, but are not limited to clogging, a loss of vacuum or negative pressure due to filling of the vacuum source **6** and or a breach, break or puncture in the aspiration system **2**, and the engagement or aspiration of non-fluid, solid or semi-solid material such as thrombus. The aspiration monitoring system **48** of FIG. 2A is configured to alert users of an aspiration system **2** about real time status of the aspiration system **2**, including operational conditions, which include: whether vacuum or negative pressure is being applied or not; flow conditions, which include whether a thrombus is engaged, whether a thrombus is being actively aspirated, whether the system is leaking air, whether the system is clogged, whether the vacuum source **6** is full and/or needs to be changed; or other potential set up issues. The real time feedback provided frees a user or operator from the need of excessive personal monitoring of the vacuum source **6**, extension tubing **10**, or other portions of the aspiration system **2**, for improper or undesired flow or operation conditions, and thus allows the user to focus more attention on the patient being treated. The user is kept aware of whether a clot is being aspirated or has been aspirated, or whether there is a clog. Additionally, the user is kept aware of whether there is too large an amount of blood being removed from the patient, or whether there are fault conditions like system leak or tubing kink. A tubing kink distal to the vacuum sensor **50** can be identified (for example by an increase in measured negative pressure) and a tubing kink proximal to the vacuum sensor **50** can be identified (for example, by a loss or degradation of the negative pressure gradient). In some cases, the user may attempt to operate the catheter with a vacuum source **6** that is already full (and thus has no significant negative pressure gradient). In some cases, a user may even forget to open the valve **8** to begin aspiration, but the aspiration monitoring system, **48** can also identify that the system is not yet functioning, and communicate a list of potential errors or specific errors (for the particular pressure waveform measured). By having the real-time awareness of the many factors related to the operating status, the procedure is made safer, the time of the procedure can be reduced, and blood loss can be reduced.

**[0116]** The pressure transducer **12** of the aspiration monitoring system **48** is configured to continuously measure and monitor the absolute pressure amplitude within the closed system of the aspiration system **2**, and also is configured to measure and monitor the relative pressure over time to detect noteworthy flow changes within the flow circuit of the

aspiration system **2**. Some changes are discernible via absolute pressure measurement, while more subtle pressure deflections can be compared to a stored library in memory. Noteworthy conditions can be signaled to the user when appropriate. In some embodiments, the unfiltered signal can be amplified by an amplifier and filtered by a filter, for example, to increase the signal-to-noise ratio. Examples of the (background) noise **57** in an unfiltered signal can be seen in FIGS. **5A-5D** (labeled in FIG. **5A**). In some embodiments, one or more algorithms can be used, as described herein, to identify particular conditions of interest.

**[0117]** FIG. 2B illustrates a second embodiment of an aspiration monitoring system **62** having a pressure transducer **12** having a vacuum sensor **50** disposed within the cavity **42** of a housing **40**. The vacuum sensor **50** can be powered by at least one battery **52**. In some embodiments, the pressure transducer **12** can be reusable, and can be configured to allow charging of the battery **52**, or of a capacitor (not shown) by direct charging methods, or by inductive power transfer methods and devices known in the art. Unlike the aspiration monitoring system **48** of FIG. 2A, the aspiration monitoring system **62** of FIG. 2B comprises a measurement device **64**, memory module **66**, and communication device **68** which are external to the pressure transducer **12**. A power module **72**, also external, can be used to power any of the measurement device **64**, memory module **66**, or communication device **68**. The communication device **68** can be any of the communication device **58a**, **58b**, **58c** described in relation to the aspiration monitoring system **48** of FIG. 2A, and are configured to produce an alert via an alert signal **70**. The communication device **68** can be portable so that it can be positioned close to the user.

**[0118]** In some embodiments, the communication device **68** can be wearable by the user. FIG. 3 illustrates an aspiration monitoring system **78** which includes an antenna **80** coupled to a measurement device **76**. The measurement device **76** is similar to the measurement device **54** of prior embodiments, except that it wirelessly sends a communication signal **84** via the antenna **80** to a corresponding antenna **82** of a communication device **74**. In some embodiments, the communication device **74** comprises a wristband which the user wears, and which can include a vibration generator or heat generator. In some embodiments, the communication device **74** comprises an audio speaker which can be attached to equipment or even to the patient or user. In some embodiments, the communication device **74** comprises an audio speaker on an earpiece or earbud that the user can wear. In some embodiments, Bluetooth® communication technology can be used. The real time feedback supplied by the aspiration monitoring system **62** can decrease the time that the aspiration system **2** is actively aspirating without being engaged with a thrombus, thus minimizing the amount of non-thrombotic blood lost by aspiration. This can be particularly beneficial in larger bore catheters, for example in catheters having a diameter of 7 French or larger. The real time feedback can also minimize the amount of total time that catheters are tracked back-and-forth through the blood vessels, minimizing potential damage to the intima of the blood vessels, dissection of the blood vessels, or distal embolization. By lowering the risk of the aspiration catheter tip getting caught (via suction) against the blood vessel wall, the distal end of the aspiration lumen can be more aggressively designed for optimized aspiration characteristics. The technique of using the aspiration catheter can additionally be

able to be performed in a more sophisticated manner, with continual or continuous knowledge of the aspiration status or negative pressure gradient sufficiency. For example, a piece of thrombus can be aspirated, followed by a "chaser" of blood aspiration, followed by another piece of thrombus, etc.

[0119] FIG. 4A illustrates the distal end 16 of an aspiration catheter 4 within a blood vessel 86 having at least one thrombus 88. The aspiration catheter 4 is being advanced in a forward direction F, but the distal end 16 of the aspiration catheter 4 has not yet reached the proximal extremity 94 of the thrombus 88. A vacuum source 6 (FIG. 1) has been coupled to the aspiration lumen 18 of the aspiration catheter 4 and activated (i.e. the valve 8 is open) causing blood 96 to be aspirated into the aspiration lumen 18 (arrows A). Turning to FIG. 5A, a corresponding curve 98 is represented for the normal fluid (e.g. blood) vacuum or negative pressure over time for the condition of FIG. 4A. The curve 98 represents vacuum or negative pressure over time sensed by the vacuum sensor 50 of any of the embodiments presented. No leaks are present and no thrombus is being evacuated, and therefore the curve 98 includes a downward slope 99 when the vacuum source 6 lowers the pressure within the cavity 42 of the pressure transducer 12 to a relatively steady state. The steady pressure curve 97 continues while blood 96 is being aspirated. As the vacuum source 6 is decoupled from the aspiration lumen 18, for example by closing the valve 8 or by detaching any two of the ports (e.g. luers), or if the vacuum source 6 fills completely with blood 96, then an upward slope 95 is measured.

[0120] The measurement device 54, 64 is configured to compare the curve 97 with information stored in the memory module 56, 66 to identify this condition. In some embodiments, the measurement device 54, 64 uses an algorithm to make the comparison. In some embodiments, the measurement device 54, 64 then sends a signal to the communication device 58a-c, 74, and the communication device 58a-c, 74 generates an appropriate alert. Communication device 58a, for example a particular color LED, can be illuminated, or an LED can flash in a particular pattern or number of flashes. Communication device 58b can create a characteristic sound, or can generate an audio message in a number of languages. For example, the audio message can state, "Thrombus encountered," or "No thrombus encountered." A different type of sound can be used for each of a plurality of "modes": "Thrombus encountered," "Actively flowing," and "No Vacuum." For example, a buzzing sound for "Thrombus encountered," a beep for "No vacuum," etc. The various characteristics of sound that can be varied include, but are not limited to timbre, or sound quality, spectrum, envelope, duration, phase, pitch (frequency), number of sounds (repetition). Communication device 58c can vibrate or heat in a characteristic pattern, for example, a certain number of repetitions or a certain frequency between repetitions. The user can determine that an additional fluoroscopic image (e.g. angiography) or other imaging modalities can be necessary to better identify the location of the thrombus 88.

[0121] FIG. 4B illustrates the distal end 16 of an aspiration catheter 4 advanced to a position such that the distal end 16 of the aspiration catheter 4 contacts the proximal extremity 94 of the thrombus 88. The corresponding curve 93 in FIG. 5B represents vacuum or negative pressure over time sensed by the vacuum sensor 50 of any of the embodiments presented. The curve 93 initially has a downward slope 99 followed by a steady pressure curve 97, as in the condition of FIG. 4A, graphed in FIG. 5A, however, when the distal

end 16 of the aspiration catheter 4 contacts the proximal extremity 94 of the thrombus 88, if the aspiration causes a portion of the thrombus 88 (for example a large or relatively hard portion) to enter and become trapped in the aspiration lumen 18, then a clog condition occurs. A similar condition occurs if the distal end 16 of the aspiration catheter 4 is caught on the thrombus 88 by a suction effect, with virtually nothing flowing through the aspiration lumen 18. In either condition, the curve 93 includes a deviation (or disturbance) in fluid pressure 91. If the clog (or stuck condition) continues, then a flat, depressed pressure 89 is measured.

[0122] The measurement device 54, 64 is configured to compare the curve 93 with information stored in the memory module 56, 66 to identify this condition. In some embodiments, the measurement device 54, 64 uses an algorithm to make the comparison. In some embodiments, a pre-set pressure differential  $\Delta P_1$  can be stored in the memory module 56, 66 as a threshold, whereby the measurement of a pressure difference 81 less than this threshold does not result in the measurement device 54, 64 commanding the communication device 58a-c, 74 to send an alert signal 60a-c, 70. In some embodiments, when the pressure difference 81 is greater than (or greater than or equal to) the pre-set pressure differential  $\Delta P_1$ , the measurement device 54, 64 then sends a signal to the communication device 58a-c, 74, and the communication device 58a-c, 74 generates an appropriate alert. Communication device 58a, for example a particular color LED, can be illuminated, or an LED can flash in a particular pattern or number of flashes. Communication device 58b can create a characteristic sound, or can generate an audio message in a number of languages. For example, the audio message can state, "Clog Condition." Communication device 58c can vibrate or heat in a characteristic pattern, for example, a certain number of repetitions or a certain frequency between repetitions. When the user realizes that the clog condition is present, the user can pull on the aspiration catheter 4 and readvance it, in an attempt to contact a portion of the thrombus 88 that can be aspirated. If a portion of the thrombus is clogged in the aspiration lumen 18, and repositioning of the aspiration catheter 4 does not produce good results, the aspiration catheter 4 can be removed and the aspiration system 2 can be repurged, for example by a positive pressurization.

[0123] FIG. 4C illustrates the distal end 16 of the aspiration catheter 4 in a general situation during which a breach in the aspiration system 2 has occurred. For example, a break, leak, puncture, pinhole, loosening, or disconnection can cause air to be pulled into the aspiration lumen 18 of the aspiration catheter 4, the cavity 42 of the pressure transducer 12, or the interior of the extension tubing 10, valve 8, or vacuum source 6. As graphed in the curve 85 of FIG. 5C, a downward slope 99 and a subsequent steady pressure curve 97 are measured, but at the point in time of the breach 87 an upward slope 83 begins.

[0124] The measurement device 54, 64 is configured to compare the curve 85 with information stored in the memory module 56, 66 to identify this condition. In some embodiments, the measurement device 54, 64 uses an algorithm to make the comparison. In some embodiments, the measurement device 54, 64 then sends a signal to the communication device 58a-c, 74, and the communication device 58a-c, 74 generates an appropriate alert. Communication device 58a, for example a particular color LED, can be illuminated, or an LED can flash in a particular pattern or number of flashes. Communication device 58b can create a characteristic sound, or can generate an audio message in a number of languages. For example, the audio message can state, "Sys-

tem Leak.” Communication device **58c** can vibrate or heat in a characteristic pattern, for example, a certain number of repetitions or a certain frequency between repetitions. Upon receiving the alert, the user will check the components of the aspiration system **2** and either fix the breach or replace one or more of the components of the aspiration system **2**. For example, in some cases, the communication device **58a-c**, **74** can alert the user when the measurement device **54**, **64** confirms a loss of applied vacuum or negative pressure, allowing the user to change or recharge the vacuum source **6**, which has become depleted (e.g. by filling with blood and/or thrombus).

**[0125]** FIG. 4D illustrates the distal end **16** of the aspiration catheter **4** during the successful aspiration of pieces or portions **90** of the thrombus **88**. In some cases, the pieces or portions **90** can follow a tortuous path **92**, due to disturbances or collisions with the inner wall of the aspiration lumen **18** while being pulled through the aspiration lumen **18**. In some cases, the pieces or portions **90** can catch and slip within the inner wall of the aspiration lumen **18**, for example, due to variance of the inner diameter of the aspiration lumen **18** along the length. Either of these situations can cause a corresponding series of increases and decreases in the pressure being sensed by the pressure transducer **12**, while the pieces or portions **90** are traveling through the aspiration lumen **18**. As graphed in the curve **79** of FIG. 5D, a downward slope **99** and a subsequent steady pressure curve **97** are measured, but as the pieces or portions **90** of thrombus **88** travel down the aspiration lumen **18** of the aspiration catheter **4**, a deviation **77** of fluid pressure comprising a one or more decreases and increases in pressure (increases and decreases in vacuum or negative pressure) is measured. As the pieces or portions **90** of thrombus **88** exit the proximal end of the aspiration lumen **18** of the aspiration catheter **4**, a second steady pressure curve **75** is measured. The duration **67** of the deviation **77** is the amount of transit of the particular significant pieces or portions **90** of thrombus **88**. The duration **67** can range quite a bit, but in some cases can be less than a second or up to about 30 seconds. A single thrombus being aspirated can cause a single decrease in pressure (a blip) which is identified by the measurement device **54**, **64**. Subsequently, this occurrence can be communicated to the user by the communication device **58a-c**, **74**. When again additional pieces or portions **90** of thrombus **88** are aspirated into and travel down the aspiration lumen **18** of the aspiration catheter **4**, another deviation **73** of fluid pressure comprising a one or more decreases and increases in pressure (increases and decreases in vacuum or negative pressure) is measured. At the end of the curve **79**, the vacuum source **6** is shown filling completely with blood **96** and the pieces or portions **90** of thrombus **88**, and so an upward slope **95** is measured.

**[0126]** The measurement device **54**, **64** is configured to compare the curve **79** with information stored in the memory module **56**, **66** to identify when the pieces or portions **90** of thrombus **88** are actively being aspirated, as in deviation **77** and deviation **73**, and when the pieces or portions of thrombus **88** are not being actively, or substantially, aspirated, as in steady pressure curve **97**, the steady pressure curve **75**, and the steady pressure curve **71**. In some embodiments, the measurement device **54**, **64** uses an algorithm to make the comparison. In some embodiments, a pre-set pressure differential  $\Delta P_2$  can be stored in the memory module **56**, **66** as a threshold, whereby the measurement of a pressure difference **69** less than this threshold does not result in the measurement device **54**, **64** commanding the communication device **58a-c**, **74** to send a first type of alert

via an alert signal **60a-c**, **70**. In some embodiments, when the pressure difference **69** is greater than (or greater than or equal to) the pre-set pressure differential  $\Delta P_2$ , the measurement device **54**, **64** then sends a signal to the communication device **58a-c**, **74**, and the communication device **58a-c**, **74** generates an appropriate alert. Communication device **58a**, for example a particular color LED, can be illuminated, or an LED can flash in a particular pattern or number of flashes. In some embodiments, the communication device **58a** can comprise a light whose intensity increases proportionally with the pressure. Communication device **58b** can create a characteristic sound, or can generate an audio message in a number of languages. For example, the audio message can state, “Thrombus being aspirated.” In some embodiments, communication device **58b** can comprise one or more noises or beeps. In some embodiments, the communication device **58b** can comprise a particular series of beeps corresponding to each different condition. For example, three short beeps can correspond to no thrombus being aspirated, while five long, loud beeps can correspond to a system leak. In some embodiments, a plurality of different tones (pitches) can be used to alert a user about different conditions. As an example, a low pitch sound can be used for a first condition (e.g. no thrombus being aspirated) and a second, higher pitch sound can be used for a second condition (e.g. a system leak). In some embodiments, a plurality of different tones can be used to alert a user about a first condition and a second plurality (e.g. in a different combination, or with additional tones) can be used to alert a user about a second condition. Communication device **58c** can vibrate or heat in a characteristic pattern, for example, a certain number of repetitions or a certain frequency between repetitions. When the user realizes that the thrombus is being aspirated, the user can choose to advance (or retract) the aspiration catheter **4**, for example with fluoroscopic visualization, along the length of the thrombus **88**, in an attempt to continue the aspiration of the thrombus **88**. In some cases, the user can choose to stop the advancement or retraction of the aspiration catheter **4** at a certain amount of time after the alert is generated, in order to allow the pieces or portions **90** of thrombus **88** to completely exit the aspiration lumen **18**. When the measurement device **54**, **64** identifies a subsequent steady pressure curve **75**, **71** that follows a deviation **77**, **73**, the measurement device **54**, **64** in some embodiments sends a signal that causes the communication device **58a-c**, **74** to generate a second type of alert via an alert signal **60a-c**, **70**. For example, in some embodiments, communication device **58b** can send an audio message that states, “Thrombus no longer being aspirated.” When the user realizes that the thrombus is no longer being aspirated, the user can advance or retract the aspiration catheter, in an attempt to contact another portion of the thrombus **88** that can be aspirated. In some embodiments, the deviation **77** can be positively identified as a true deviation indicating thrombus being actively aspirated, pressure difference **69** is between about 700 pascal and about 1700 pascal. In some embodiments, the deviation **77** can be positively identified as a true deviation indicating thrombus being actively aspirated, pressure difference **69** is between about 1000 pascal and about 1300 pascal. In some embodiments, the deviation **77** can be positively identified as a true deviation indicating thrombus being actively aspirated, pressure difference **69** is about 1138 pascal. The pressure difference **69** can be measured by determining a baseline pressure **63** and a peak pressure **61** and determining the absolute value difference. For example:

Absolute value difference (*AVD*) =

$$|(-89,631 \text{ pascal}) - (-90,769 \text{ pascal})| = 1138 \text{ pascal}$$

[0127] Or for example:

Absolute value difference (*AVD*) =

$$|(-43,710 \text{ pascal}) - (-45,102 \text{ pascal})| = 1281 \text{ pascal}$$

[0128] The pressure difference **81** (FIG. 5B) can also represent a deviation that can be identified in a similar manner, after which the communication device **58a-c**, **74** generates an appropriate alert, such as, "Clog condition."

[0129] Because vacuum or negative pressure has a nominal value less than zero, the peak pressure **61**, as shown in FIG. 5D, is actually a lower number than the baseline pressure **63**. In some embodiments, the measurement device **54**, **64** can also be configured to make a comparison, for example by using an algorithm, between a stored differential time  $t_1$  and a duration **65** of a single one of the more or more decreases and increases in pressure in the deviation **77**. For example, in some embodiments, the deviation can be positively identified as a true deviation indicating thrombus being actively aspirated, if the duration is between about 0.001 seconds and about 0.50 seconds. In some embodiments, the deviation can be positively identified as a true deviation indicating thrombus being actively aspirated, if the duration is between about 0.005 seconds and about 0.10 seconds. In some embodiments, the deviation can be positively identified as a true deviation indicating thrombus being actively aspirated if the duration is between about 0.05 seconds and about 0.20 seconds. In some embodiments, the measurement device **54**, **64** is configured to recognize deviation **77** after two or more decreases and increases in pressure are measured. In some embodiments, the measurement device **54**, **64** is configured to recognize deviation **77** after five or more decreases and increases in pressure are measured. In some embodiments, the measurement device **54**, **64** is configured to recognize deviation **77** after ten or more decreases and increases in pressure are measured.

[0130] The baseline pressure **63** can in some embodiments be predetermined and can be stored in the memory module **56**, **66**. In some embodiments, the baseline pressure **63** can be stored in the memory module **56**, **66** during the manufacture of the aspiration monitoring system **48**, **62**, **78**, but the baseline pressure **63** can also be input by the user prior to or during a particular procedure. In some embodiments, there may be a baseline pressure differential, which is compared to a difference in the output of two different pressure sensors. In some embodiments, the baseline pressure **63** can be determined or otherwise defined by the measurement device **54**, **64**, **76** based on averaging of a particular number of samples of measured pressure. The baseline pressure **63** can be constructed as a moving average, such as a running average or rolling average. Several types of moving average can be used, including a simple moving average, a cumulative moving average, a weighted moving average, or an exponential moving average. In any of these cases, a threshold can be determined by the measurement device **54**, **64**, **76** based on the determined baseline pressure **63** and a known pressure differential  $\Delta P$ . In some case, a pressure differential  $\Delta P$  can even be calculated by the

measurement device **54**, **64**, **76** based on the determined baseline pressure **63** and a known threshold.

[0131] Insertion of the pressure transducer **12** in line in either the embodiment of FIG. 2A or the embodiment of FIG. 2B does not measurably change performance characteristics of the aspiration system **2**, because the cavity **42** is relatively short and has a relatively large inner diameter, and thus is not a significant source of fluid flow resistance. In some embodiments, the inner diameter can be between about 2.2 mm (0.086 inches) and about 3.2 mm (0.125 inches). In some embodiments, the measurement device **54**, **64**, **76** need not include a microprocessor, as pre-defined set points (e.g., for certain thresholds) can be included in firmware, microcontroller, or other locations. In some embodiments, including but not limited to the embodiment of FIG. 2B, the pressure transducer **12** can be an off-the-shelf blood pressure monitor system, which is modified or augmented with other components. In some embodiments an off-the-shelf blood pressure monitor system can be used as the output of the aspiration monitoring system **48**, **62**, **78**. In some embodiments, an aspiration catheter **4** can have a pressure transducer in the distal end **16**. This pressure transducer can be used as the pressure transducer **12** of the aspiration monitoring system **48**, **62**, **78**. In some embodiments, a pressure sensor can be located within a Tuohy-Borst valve, and introducer sheath, a guiding catheter, or another component of the system through which is in fluid communication with the aspiration lumen **18**. In some embodiments, the pressure sensor can be located anywhere within the aspiration lumen of the aspiration catheter.

[0132] In some embodiments, instead of an LED, the visual alert is provided by a communication device **58a** comprising a display which displays visual messages of text in a particular language, for example, "Thrombus encountered," "No thrombus encountered," "Clog condition," "System leak," "Loss of vacuum," "Thrombus being aspirated," or "Thrombus no longer being aspirated." The visual messages can be combined with any of the other alert signals **60a-c**, **70** described herein. The aspiration monitoring system **48**, **62**, **78** described herein give real time awareness to users performing aspiration procedures, such as the removal of thrombus via an aspiration system **2**. One skilled in the art will recognize that by knowing the real time condition of the aspiration system **2**, the user is able to immediately make changes to the procedure in order to optimize results, increase safety for the patient and/or medical personnel, reduce costs (e.g. number of vacuum sources **6** required), and reduce procedure time (also a cost benefit). Because the user is typically performing multiple tasks during an aspiration procedure, the sensory aid provided by the aspiration monitoring system **48**, **62**, **78** allows the user to focus on these tasks without having to continually attempt to monitor conditions which are often difficult to visually monitor. The user can also modify and control the aspiration monitoring system **48**, **62**, **78** via an input **59** (FIG. 2B), which can comprise a data entry module, keyboard, or a series of buttons with a display. The input **59** can in some embodiments comprise an auditory input which accepts voice commands. Alternatively, the user can input information and control the aspiration monitoring system, **48**, **62**, **78** remotely. Some of the alerts which the user can select or deselect in the aspiration monitoring system **48**, **62**, **78** include, but are not limited to: whether the aspiration system **2** is potentially blocked or clogged, or is flowing normally; whether thrombus has been contacted or not; whether a clog has occurred; whether the vacuum source **6** is adequate, or whether it has been depleted and requires replacement;

whether there is a leak in the aspiration system 2; whether setup or connection of the components of the aspiration system 2 was done correctly or incorrectly; whether to advance the catheter distally; whether to retract the catheter; whether to continue moving the catheter at the same speed; whether to increase or decrease the speed of catheter advancement; whether thrombus is actively being aspirated; and whether thrombus stops being actively aspirated. As the user becomes familiar with the aspiration monitoring system 48, 62, 78, the user can even begin to make certain responses to the system subconsciously. For example, a user can automatically pull back the catheter upon hearing a clot warning signal (e.g., three beeps), and can automatically begin advancing the catheter and/or start fluoroscopic visualization upon hearing a free blood flow signal (e.g., two beeps). By being “at one” with the aspiration monitoring system 48, 62, 78 and the catheter, the user optimizes reactions and actions. This can be helpful improving the skill of having the catheter take a small “bite” of thrombus, and following the “bite” with a “chaser” of some fast flowing blood, the clean/open the lumen. This would also help minimize the chance of clogging, and would in turn reduce maintenance or corrections of the system (removing the catheter, flushing the lumen outside of the patient, replacing the catheter). The overall experience for the user is improved, as the user receives instant gratification for good results, and is instantly notified of errors or instances for concern.

[0133] In some embodiments, alternate power sources can be used, for example, standard AC power with or without an AC/DC convertor; direct connection to existing equipment (e.g. vacuum pumps, etc.); solar power. The aspiration monitoring system 48, 62, 78 can be packaged sterile or can be resterilizable by techniques known by those skilled in the art. In some embodiments, flow or volume gauges can be used in conjunction with or instead of the pressure gauge 12, in order to determine, for example, a clog, or a change in the amount of vacuum or negative pressure. In some embodiments, the input 59, power module 72, measurement device 64, memory module 66, and communication device 68 (e.g., of FIG. 2B) can all be incorporated into a single external device, which can in some cases be sold separately. In some embodiments, the external device can also have other functions, such as providing aspiration and/or injection (negative pressure and/or positive pressure) to a catheter. In other embodiments, the external device can comprise some, but not all of the input 59, power module 72, measurement device 64, memory module 66, and communication device 68. For example, in some embodiments, a communication device 58 (FIG. 2A) can replace the external communication device 68, and can be carried on the aspiration monitoring system 48, while the input 59, power module 72, measurement device 64, memory module 66 (FIG. 2B) are incorporated into a single external device. A number of combinations are possible, as described in more detail herein.

[0134] Though aspiration of thrombus has been described in detail, the aspiration monitoring system 48, 62, 78 has utility in any aspiration application wherein heterogeneous media is being aspirated. This can include the aspiration of emboli (including not thrombotic emboli) from ducts, vessels, or cavities of the body, or even from solid or semi-solid portions of the body, including, but not limited to, portions of fat, breasts, and cancerous tissue.

[0135] In some embodiments, the aspiration system 2 is be provided to the user as a kit with all or several of the components described, while in other embodiments, only the aspiration monitoring system 48 is provided. Though dis-

cussion herein includes embodiments for aspiration of thrombus and blood, the definition of the word “fluid” should be understood throughout to comprise liquids and gases.

[0136] In some embodiments, an additional or alternate sensor can be used to monitor flow conditions for the notification of the user, including, but not limited to: a Doppler sensor, an infrared sensor, or a laser flow detection device. In some embodiments, an externally-attached Doppler sensor can be employed. In some embodiments, an infrared sensor or a laser flow detection device can be employed around the extension tubing 10.

[0137] Additional embodiments allow real time communication of the particular value of fluid pressure (for example the level of vacuum or negative pressure) measured by the sensor 50. For example, as the negative pressure gradient increases, an audible sound can increase in sound intensity or in sound pressure level (dB) proportionally. Or, as the negative pressure gradient increases, the pitch (frequency) of an audible sound can made to rise, and as the negative pressure gradient decreases, the pitch can be made to fall (as does a siren). By controlling either the amplitude of a signal or the frequency of a signal by making them proportional to the fluid pressure, the system can give a user a real-time sense of whether the negative pressure gradient is increasing, decreasing, or staying the same, as well as whether the pressure is close to zero or quite different from zero. When an audible sound is used as the signal, the user's eyes can remain focused on the procedure, whether by viewing a monitor of fluoroscopic images, the patient, or a separate piece of equipment.

[0138] FIG. 6 illustrates a graph 800 of time (x-axis) and multiple variables (y-axis). A pressure curve 802 shows a vacuum or negative pressure being applied at a pressure drop 808, and a maintenance of vacuum or negative pressure 810a with a decrease in vacuum or negative pressure 812 and an increase in vacuum or negative pressure 814. A removal of vacuum or negative pressure 816 is shown at the end of the pressure curve 802. In some cases, the decrease in vacuum or negative pressure 812 can be caused by a temporary or permanent leak or detachment within the system or by filling of the vacuum source (e.g., syringe). In FIG. 6, the decrease in vacuum or negative pressure 812 is shown as temporary, as a subsequent maintenance of vacuum or negative pressure 810b is illustrated. The increase in vacuum or negative pressure 814 can in some cases be caused by thrombus being sucked through the system and can occur for a short or long amount of time, and can be steady or intermittent. Though the amount of vacuum or negative pressure applied in the pressure curve 802 varies, in some embodiments, it may only be desirable to show to a user only whether the vacuum or negative pressure is generally being applied or not being applied. The measurement device 54, 64, 76 can be configured to apply an algorithm to the signal from the vacuum sensor 50 (pressure sensor) that calculates an inverse value, represented by the dashed curve 804. The measurement device 54, 64, 76 further can apply an algorithm that increases, amplifies or otherwise augments the signal for ease of identification, for example within the human range of audible identification (hearing). For example, a modified signal curve 806 can be created that has the following general mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 802.

$$\text{Sound Pressure Level (dB)} = A + B \times (1/\text{fluid pressure})$$

[0139] where A is a first constant, and

[0140] B is a second constant

[0141] In one particular example, a modified signal curve 806 can be created that has the following mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 802.

$$\text{Sound Pressure Level (dB)} = 70 + 20 \times (1/\text{fluid pressure (kPa)})$$

[0142] where dB is units in decibels, and

[0143] kPa is units of kiloPascal

[0144] The modified signal curve 806 can be constructed of an algorithm such that the sound pressure level drops below the audible level of human hearing at relatively small amounts of vacuum or negative pressure, thus giving the user an “on/off” awareness of the vacuum or negative pressure being applied.

[0145] FIG. 7 illustrates a graph 820 of time (x-axis) and multiple variables (y-axis). A pressure curve 822 shows a vacuum or negative pressure being applied at a pressure drop 828, and a maintenance of vacuum or negative pressure 830a with a decrease in vacuum or negative pressure 832 and an increase in vacuum or negative pressure 834. A removal of vacuum or negative pressure 836 is shown at the end of the pressure curve 822. In some cases, the decrease in vacuum or negative pressure 832 can be caused by a temporary or permanent leak or detachment within the system or by filling of the vacuum source (e.g., syringe). In FIG. 7, the decrease in vacuum or negative pressure 832 is shown as temporary, as a subsequent maintenance of vacuum or negative pressure 830b is illustrated. The increase in vacuum or negative pressure 834 can in some cases be caused by thrombus being sucked through the system and can occur for a short or long amount of time, and can be steady or intermittent. In some cases or configurations, it may be desirable for the user to have a very specific real-time or close to real-time characterization of the amount or level of vacuum (negative pressure gradient in general) being applied. The measurement device 54, 64, 76 can be configured to apply an algorithm to the signal from the vacuum sensor 50 (pressure sensor) that calculates an absolute value, represented by the dashed curve 824. The measurement device 54, 64, 76 further can apply an algorithm that increases, amplifies or otherwise augments the signal for ease of identification, for example within the human range of audible identification (hearing). For example, a modified signal curve 826 can be created that has the following general mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 822.

$$\text{Sound Pressure Level (dB)} = A + B \times |(\text{fluid pressure})|$$

[0146] where A is a first constant, and

[0147] B is a second constant

[0148] In one particular example, a modified signal curve 826 can be created that has the following mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 822.

$$\text{Sound Pressure Level (dB)} = 2 \times |(\text{fluid pressure (kPa)})|$$

[0149] where dB is units in decibels and,

[0150] kPa is units of kiloPascal

[0151] The modified signal curve 826 can be constructed of an algorithm such that the sound pressure level seems to the user to follow the amount of vacuum or negative pressure being applied, thus becoming louder as the vacuum or negative pressure is increased.

[0152] FIG. 8 illustrates a graph 840 of time (x-axis) and multiple variables (y-axis). A pressure curve 842 shows a vacuum or negative pressure being applied at a pressure drop 848, and a maintenance of vacuum or negative pressure 850a with a decrease in vacuum or negative pressure 852 and an increase in vacuum or negative pressure 854. A removal of vacuum or negative pressure 856 is shown at the end of the pressure curve 842. In some cases, the decrease in vacuum or negative pressure 852 may be caused by a temporary or permanent leak or detachment within the system or by filling of the vacuum source (e.g., syringe). In FIG. 8, the decrease in vacuum or negative pressure 852 is shown as temporary, as a subsequent maintenance of vacuum or negative pressure 850b is illustrated. The increase in vacuum or negative pressure 854 may in some cases be caused by thrombus being sucked through the system and may occur for a short or long amount of time, and can be steady or intermittent. As mentioned, in some cases or configurations, it can be desirable for the user to have a very specific real-time or close to real-time characterization of the amount or level of vacuum (negative pressure gradient in general) being applied. The measurement device 54, 64, 76 can be configured to apply an algorithm to the signal from the vacuum sensor 50 (pressure sensor) that calculates an absolute value, represented by the dashed curve 844. The measurement device 54, 64, 76 further can apply an algorithm that determines a frequency of an audible sound (or pitch), for example within the human range of audible identification (hearing), that varies within the human range of audible frequencies. For example, a modified signal curve 846 can be created that has the following general mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 842.

$$\text{Sound Frequency (Hz)} = A + B \times |(\text{fluid pressure})|$$

[0153] where A is a first constant, and

[0154] B is a second constant

[0155] In one particular example, a modified signal curve 846 can be created that has the following mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 842.

$$\text{Sound Frequency (Hz)} = 50 \times |(\text{fluid pressure (kPa)})|$$

[0156] where Hz is Hertz (1/second), and

[0157] kPa is units of kiloPascal

[0158] The modified signal curve 846 can be constructed of an algorithm such that the sound frequency seems to the user to follow the amount of vacuum or negative pressure being applied. In this embodiment, the pitch of the sound

becomes “higher” when vacuum is increased (fluid pressure decreases), and “lower” when the vacuum or negative pressure is decreased. Alternatively, the opposite can instead be chosen, wherein the pitch of the sound becomes lower when vacuum or negative pressure is increased.

[0159] FIG. 9 illustrates a graph 860 of time (x-axis) and multiple variables (y-axis). A pressure curve 862 shows a vacuum or negative pressure being applied at a pressure drop 868, and a maintenance of vacuum or negative pressure 870 with a one or more decreases and increases in pressure 872. These one or more decreases and increases in pressure 872 (or increases and decreases in vacuum or negative pressure) can represent, in some instances, clot being sucked through aspiration lumen of an aspiration catheter. In some cases, a single decrease in pressure 873 (increase in vacuum or negative pressure) can occur. The single decrease in pressure 873 can in some cases be extended in duration, as shown in FIG. 9, as can any one of the one or more decreases and increases in pressure 872. In some cases or configurations, it can be desirable for the user to have a very specific real-time or close to real-time characterization of the instances when these small perturbations are occurring, as they can correspond to the catheter finding and aspirating a portion of thrombus. The measurement device 54, 64, 76 be configured to apply an algorithm that determines a frequency of an audible sound (or pitch), for example within the human range of audible identification (hearing), that varies within the human range of audible frequencies. For example, a modified signal curve 866 can be created that has the following general mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 862.

$$\text{Sound Frequency (Hz)} = A + B \times (\text{fluid pressure})$$

[0160] where A is a first constant, and

[0161] B is a second constant

[0162] In one particular example, a modified signal curve 866 can be created that has the following mathematical relationship with the signal from the vacuum sensor 50 represented by the pressure curve 862.

$$\text{Sound Frequency (Hz)} = 40 \times (\text{fluid pressure (kPa)})$$

[0163] where Hz is Hertz (1/second), and

[0164] kPa is units of kiloPascal

[0165] It should be noted that in this equation, no absolute value is used, but rather the actual value of fluid pressure. Or in some cases, an absolute (or negative) value can be used.

[0166] The modified signal curve 866 can be constructed of an algorithm such that the sound maintains a steady pitch until the clot is being sucked through the catheter, at which time the pitch changes slightly, but distinctly, away from a steady pitch. For example, in some embodiments, the pitch can change between about 20 Hz and about 2000 Hz to correspond to a pressure change of between about one kPa to about two kPa, or between about 40 Hz and about 80 Hz.

[0167] In any of the examples, the modification of signals can include any type of signal conditioning or signal modification that can be performed, including, but not limited to filtering, amplification, or isolation. The modified signal curve 806, 826, 846, 866 is used to determine the output signal to be generated by the communication device 58, 68,

74. As mentioned, if the output signal of the communication device 58, 68, 74 is configured to be an audible sound, the sound pressure level can be varied, or the sound frequency can be varied. In some embodiments, the output signal of the communication device 58, 68, 74 can have both its sound pressure level and sound frequency varied. In one embodiment, the sound frequency varies continuously in proportion to fluid pressure, but at one or more particular thresholds of fluid pressure, the sound pressure level can be caused to vary quite suddenly and strikingly. Thus, there is a two-part communication occurring, a continuous real-time status indicator, with an intermittent, alert indicator (failure, danger, etc.). In some cases, the continuous real-time status indicator can represent a first continuous signal and the alert indicator can represent a second alert signal. In other cases, the continuous real-time status indicator and the alert indicator can be combined or integrated into the same signal. In some embodiments, other characteristics of psychoacoustics can be varied using variable sound generation devices. In some embodiments, the spectral envelope can be varied. In some embodiments, timbre can be changed to varies levels between light and dark, warm and harsh, or different noise “colors” (pink, white, blue, black, etc.).

[0168] Though an audible output from the communication device 58, 68, 74 has been described with the examples from FIGS. 6-9, other communication signals can be used, including visual or tactile signals. Tactile signals can also include vibration devices or heat generation devices, either of which could be varied (as described) in relation to the measured fluid pressure. Either the amplitude or the frequency could analogously be varied in communication signals that include signals other than the audible signals already described. For example, the intensity of a light can be varied, or the frequency (e.g., color) of a light can be varied. The amplitude of displacement of a vibration device can be varied (or other techniques that vary the vibration intensity) or the frequency of the vibration can be varied.

[0169] In some cases, a pseudo-continuous analog can be used in place of a truly variable output. For example, instead of a single light whose intensity is continuously varied, an array of multiple lights, for example and array comprising multiple LEDs, can be used, with an increased number of LEDs being lit when the level of vacuum or negative pressure is increased, and a decreased number of LEDs being lit when the level of vacuum or negative pressure is decreased. The same can be possible with an array comprising multiple vibrating elements, wherein more elements begin vibrating upon an increase or decrease, depending on the application, of fluid pressure.

[0170] In any of the embodiments described in relation to FIGS. 6-9, the equations for sound pressure level or for sound frequency which depend on fluid pressure as a variable, can depend on actual measured fluid pressure, or an absolute value of actual measured fluid pressure, but can also use measured fluid pressure in an alternative manner. For example, with a baseline pressure 63 either pre-set, pre-determined, or determined or calculated by any other method (averaging, etc.), the differential between the measured pressure and the baseline pressure 63 can be used as the variable on which to base the particular dependency (e.g., proportionality).

[0171] Thus, a base mathematical relationship used with the proportionality described with respect to the embodiment of FIG. 6 can be represented as:

$$\text{Sound Pressure Level (dB)} = A + B \times (1/\Delta P)$$

- [0172] where A is a first constant,
  - [0173] B is a second constant, and
  - [0174]  $\Delta P$  is a difference or differential between a baseline pressure and a measured fluid pressure.
- [0175] Likewise, a base mathematical relationship used with the proportionality described with respect to the embodiment of FIG. 7 can be represented as:

$$\text{Sound Pressure Level (dB)} = A + B \times |(\Delta P)|$$

- [0176] where A is a first constant,
  - [0177] B is a second constant, and
  - [0178]  $\Delta P$  is a difference or differential between a baseline pressure and a measured fluid pressure.
- [0179] Likewise, a base mathematical relationship used with the proportionality described with respect to the embodiment of FIG. 8 can be represented as:

$$\text{Sound Frequency (Hz)} = A + B \times |(\Delta P)|$$

- [0180] where A is a first constant,
  - [0181] B is a second constant, and
  - [0182]  $\Delta P$  is a difference or differential between a baseline pressure and a measured fluid pressure.
- [0183] Likewise, a base mathematical relationship used with the proportionality described with respect to the embodiment of FIG. 9 can be represented as:

$$\text{Sound Frequency (Hz)} = A + B \times (\Delta P)$$

- [0184] where A is a first constant,
  - [0185] B is a second constant, and
  - [0186]  $\Delta P$  is a difference or differential between a baseline pressure and a measured fluid pressure.
- [0187] A pressure transducer 912 of an aspiration monitoring system 900 is illustrated in FIG. 10, for coupling to an aspiration system including an aspiration catheter 4. The pressure transducer 912 includes a housing 40, a first port 44, a second port 46 and a cable 902 for carrying a signal. The cable 902 includes an interface 904, or plug, which is configured to connect to a port 906 of a console 908 of the aspiration monitoring system 900. The housing 40 of the pressure transducer 912 includes a cavity 42 extending between the first port 44 and the second port 46. The console 908 is powered by a power module 972, which is connected to the console 908, and can comprise a source of AC or DC power. The console 908 can include a measurement device 964, a memory module 966 and a communication device 968, which can be coupled to each other as described in the prior embodiments and configured such that the communication device 968 is capable of creating a signal 970, which can be an alert signal, a continuous signal, a combined signal, or other type of signal. The console 908 can also include wired or wireless connections to other interfaces or displays which can be found in health care sites, such as a monitor 931. In some embodiments, the monitor 931 can be a monitor which also displays fluoroscopy or angiogram

images, or a monitor which also displays electrocardiography or blood pressure graphics or other information. The monitor 931 can have a portion that maintains the status of the aspiration. For example, it can read "Thrombus being aspirated" or "No thrombus detected." The pressure transducer 912 (housing 40, ports 44, 46, cable 902, interface 904) can be sold sterile, and can be configured to output a signal that is received by the console 908, for example the measurement device 964 of the console 908. The pressure transducer 912 can have its own internal source of power (e.g., the battery 52 in FIG. 2A), or can be powered by its connection to the console 908, or alternatively, by its connection to the aspiration catheter 4, or even the extension tubing 10. In some embodiments, the console 908 can be configured to identify and/or recognize the pressure transducer 912, for example, to recognize the particular model of the pressure transducer 912. In some embodiments, the console 908 can be configured to measure a resistance between two electrical contacts in the pressure transducer 912 in order to identify the type (e.g., model) of pressure transducer. In some embodiments, the console 908 can be configured to read an RFID chip on the pressure transducer 912. The console 908 can also be configured to connect to two or more different models of pressure transducer. The port 906, can comprise at least one port, which can comprise two or more ports, each port configured to allow connection of a different model of pressure transducer.

[0188] An aspiration system 1000 in FIG. 11 includes an aspiration console 1001 having a connector 1002, or hub, (e.g., male luer) for connecting to an aspiration catheter 4, for example, to a connector 22 (e.g., female luer) of the aspiration catheter 4. The aspiration console 1001 is powered by a power module 972, which is connected to the aspiration console 1001, and can comprise a source of AC or DC power. The aspiration console 1001 can include a canister 1006 for collecting the aspirated materials, and can include a vacuum pump 1004 for creating a vacuum or negative pressure with which to create the aspiration. Tubing 1008 can be connected between the canister 1006 and the connector 1002. In some embodiments, the canister 1006 is removable or replaceable. An aspiration monitoring system 900 includes a pressure sensor 1010 (e.g., a vacuum sensor) in fluid communication with the tubing 1008. The tubing 1008 can instead comprise a lumen formed inside fabricated parts. The aspiration monitoring system 900 is shown in more detail in FIG. 12, and can include some or all of the features described in relation to FIG. 10. The aspiration console 1001 can also include wired or wireless connections to other interfaces or displays which can be found in health care sites, such as a monitor 931. In some embodiments, the monitor 931 can be a monitor which also displays fluoroscopy or angiogram images, or a monitor which also displays electrocardiography or blood pressure graphics or other information. By combining all communication related to the procedure on or at a single monitor or single monitor location, uninterrupted focus can be achieved by the user, who can be freely dedicated to the safe advancement and placement of the aspiration catheter in proximity to the thrombus.

[0189] A system for forced (or assisted) aspiration 1100 in FIG. 13 includes an aspiration/injection console 1101 having a first connector 1016, or hub, (e.g., male luer) for connecting to an injection lumen 1020 of a forced aspiration catheter 1013, and a second connector 1012, or hub (e.g., male luer) for connecting to an aspiration lumen 1018 of the forced aspiration catheter 1013. The first connector 1016 is configured to connect to connector 1024 (e.g., female luer) of a

y-connector 1022 and the second connector 1012 is configured to connect to connector 1026 of the y-connector 1022 at a proximal end 14 of the forced aspiration catheter 1013. The aspiration/injection console 1101 is powered by a power module 972, which is connected to the aspiration console 1101, and can comprise a source of AC or DC power. The aspiration console 1101 can include a canister 1106 for collecting the aspirated materials, and can include a vacuum pump 1104 for creating a vacuum or negative pressure with which to create the aspiration. Tubing 1108 can be connected between the canister 1106 and the connector 1012. A positive pressure pump 1014 is coupled to a fluid source 1032 (e.g., a saline bag) and is configured to inject infusate out the connector 1016 at a high pressure. An aspiration monitoring system 900 includes a pressure sensor 1110 (e.g., a vacuum sensor) in fluid communication with the tubing 1108. The tubing 1108 can instead comprise a lumen formed inside fabricated parts. The aspiration monitoring system 900 is shown in more detail in FIG. 14, and can include some or all of the features described in relation to FIG. 10. At a distal end 16 of the forced aspiration catheter 1013, the injection lumen 1020 terminates in an orifice 1028, which is configured to create a jet 1030 formed from the high pressure infusate exiting the orifice 1028. The jet 1030 enters the aspiration lumen 1018, thus creating suction at the distal end 16 of the forced aspiration catheter 1013, which forces materials (e.g., thrombus) into the aspiration lumen 1018, and into the canister 1106. The aspiration/injection console 1101 can also include wired or wireless connections to other interfaces or displays which can be found in health care sites, such as a monitor 931. In some embodiments, the monitor 931 can be a monitor which also displays fluoroscopy or angiogram images, or a monitor which also displays electrocardiography or blood pressure graphics or other information.

[0190] In an alternative embodiment, the forced aspiration catheter 1013 of the aspiration catheter 4 can have an additional lumen or guide channel for placement of an additional device or tool. In some embodiments, the guidewire lumen 26 can be used as this additional lumen, and can extend the entire length or most of the length of the catheter, so that the lumen is accessible from the proximal end 14. The additional device or tool can comprise a laser fiber, a mechanical screw, a vibrating wire or a variety of other modalities for disrupting thrombus or other material.

[0191] In any of the embodiments presented, the system can be configured so that most or all of the components are supplied together. For example, a catheter and an aspiration monitoring system that are permanently attached to each other. In some embodiments, the aspiration catheter and/or the aspiration monitoring system can include configurations that purposely make it difficult to reprocess (e.g., clean or resterilize) them, thus protecting from potential uses that are not recommended or warranted, and which can risk patient infection and/or device malfunction. For example, the sensor or the portion adjacent the sensor can be purposely difficult to access or clean. Alternatively, one or more batteries can be impossible to access or change.

[0192] In some embodiments, it can be desired to have other descriptive warnings that can be tied to pressure measurement or pressure measurement combined with another measured attribute. For example, if a sensor (accelerometer or temperature sensor) within the aspiration catheter is used to detect catheter movement, a change in this sensor can be tied to the pressure sensor. In this manner, a catheter that is engaged with a thrombus at its tip and is

moved (e.g., begins to be pulled out of the patient) can then cause a warning: "Warning, do not move catheter; risk of thromboembolus."

[0193] FIG. 15 is a diagrammatic figure depicting an assisted aspiration system 510. The aspiration system 510 includes a remote hand piece 512 that contains a fluid pump 526 and an operator control interface 506. In one contemplated embodiment, the system 510 is a single use disposable unit. The aspiration system 510 can also include extension tubing 514, which contains a fluid irrigation lumen 502 and an aspiration lumen 504, and which allows independent manipulation of a catheter 516 without requiring repositioning of the hand piece 512 during a procedure performed with the aspiration system 510. Extension tubing 514 can also act as a pressure accumulator. High pressure fluid flow from the pump 526, which can comprise a displacement pump, pulses with each stroke of the pump 526 creating a sinusoidal pressure map with distinct variations between the peaks and valleys of each sine wave. Extension tubing 514 can be matched to the pump 526 to expand and contract in unison with each pump pulse to reduce the variation in pressure caused by the pump pulses to produce a smooth or smoother fluid flow at tip of catheter 516. Any tubing having suitable compliance characteristics can be used. The extension tubing 514 can be permanently attached to the pump 526 or it can be attached to the pump 526 by a connector 544. The connector 544 is configured to ensure that the extension tubing 514 cannot be attached to the pump 526 incorrectly.

[0194] An interface connector 518 joins the extension tubing 514 and the catheter 516 together. In one contemplated embodiment, the interface connector 518 can contain a filter assembly 508 between high pressure fluid injection lumen 502 of the extension tubing 514 and a high pressure injection lumen 536 of the catheter 516 (FIG. 17). The catheter 516 and the extension tubing 514 can be permanently joined by the interface connector 518. Alternatively, the interface connector 518 can contain a standardized connection so that a selected catheter 516 can be attached to the extension tubing 514. In some embodiments, the filter assembly 508 can be removably coupled to the extension tubing 514 by a quick disconnect connection. A pressure transducer of an embodiment of the aspiration monitoring system presented herein can be located at a point along the aspiration lumen 504 or any extension of the aspiration lumen 504.

[0195] Attached to the hand piece 512 are a fluid source 520 and a vacuum source 522. A standard hospital saline bag can be used as fluid source 520; such bags are readily available to the physician and provide the necessary volume to perform the procedure. Vacuum bottles can provide the vacuum source 522 or the vacuum source 522 can be provided by a syringe, a vacuum pump or other suitable vacuum source. The filter assembly 508 serves to filter particulate from the fluid source 520 to avoid clogging of the high pressure injection lumen 536 and an orifice 542 (FIG. 17). As described herein, distal sections of the high pressure injection lumen 536 can be configured with small inner diameters, and to the filter assembly 508 serves to protect their continuing function. By incorporating one of a variety of catheters 516 into the assisted aspiration system 510, for example with varying lumen configurations (inner diameter, length, etc.), a variety of aspiration qualities (aspiration rate, jet velocity, jet pressure) can be applied in one or more patients. These aspiration qualities can be further achieved by adjustment of the pump 526, to modify pump characteristics (flow rate, pump pressure). In some embodiments, the catheter 516 can be used manually, for example, without the

pump **526**, and controlled by hand injection. The manual use of the catheter **516** can be appropriate for certain patient conditions, and can serve to reduce the cost of the procedure.

[0196] In one contemplated embodiment, the catheter **516** has a variable stiffness ranging from stiffer at the proximal end to more flexible at the distal end. The variation in the stiffness of the catheter **516** can be achieved with a single tube with no radial bonds between two adjacent tubing pieces. For example, the shaft of the catheter **516** can be made from a single length of metal tube that has a spiral cut down the length of the tube to provide shaft flexibility. Variable stiffness can be created by varying the pitch of the spiral cut through different lengths of the metal tube. For example, the pitch of the spiral cut can be lower (where the turns of the spiral cut are closer together) at the distal end of the device to provide greater flexibility. Conversely, the pitch of the spiral cut at the proximal end can be greater (where the turns of the spiral cut are further apart) to provide increased stiffness. A single jacket covers the length of the metal tube to provide for a vacuum tight (air tight, outside to inside) catheter shaft. Other features of catheter **516** are described with reference to FIG. 17, below.

[0197] FIG. 16 is a diagrammatic view showing more detail of the hand piece **512** and the proximal portion of assisted catheter aspiration system **510**. The hand piece **512** includes a control box **524** where the power and control systems are disposed. The pump **526** can be a motor driven displacement pump that has a constant output. This pump displaces fluid to catheter volume, along with the location of the orifice **542** (exit) of the catheter high pressure lumen **536** within the aspiration lumen **538** (FIG. 17), ensures that no energy is transferred to the patient from the saline pump as all pressurized fluid is evacuated by the aspiration lumen. A prime button **528** is mechanically connected to a prime valve **530**. When preparing the device for use, it is advantageous to evacuate all air from the pressurized fluid system to reduce the possibility of air embolization. By depressing the prime button **528**, the user connects the fluid source **520** to the vacuum source **522** via the pump **526**. This forcefully pulls fluid (for example 0.9% NaCl solution, or “saline”, no “normal saline”, or heparinized saline) through the entire pump system, removing all air and positively priming the system for safe operation. A pressure/vacuum valve **532** is used to turn the vacuum or negative pressure on and off synchronously with the fluid pressure system. One contemplated valve **532** is a ported one-way valve. Such a valve is advantageous with respect to manual or electronic valve systems because it acts as a tamper proof safety feature by mechanically and automatically combining the operations of the two primary systems. By having pressure/vacuum valve **532**, the possibility of turning the vacuum or negative pressure on without activating the fluid system is eliminated.

[0198] The operator control interface **506** is powered by a power system **548** (such as a battery or an electrical line), and can comprise an electronic control board **550**, which can be operated by a user by use of one or more switches **552** and one or more indicator lamps **554**. The control board **550** also monitors and controls several device safety functions, which include over pressure and air bubble detection and vacuum or negative pressure charge. A pressure sensor **564** monitors pressure, and senses the presence of air bubbles. Alternatively, an optical device **566** can be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed to produce that pressure. Consequently, if the electric current required by pump **526** exceeds a preset limit, the control board will disable the pump by cutting power to it. Air bubble detection

can also be monitored by monitoring the electrical current required to drive the pump at any particular moment. In order for a displacement pump **526** to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump **526** or connecting system (including the catheter **516** and the extension tubing **514**). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. The control board monitors the pump current for any abrupt downward change that can indicate that air has entered the system. If the rate of drop is faster than a preset limit, the control board will disable the pump by cutting power to it until the problem is corrected. Likewise, a block in the high pressure lumen **536**, which can be due to the entry of organized or fibrous thrombus, or a solid embolus, can be detected by monitoring the electrical current running the pump **526**. In normal use, the current fluxuations of the pump **526** are relatively high. For example, the pump can be configured so that there is a variation of 200 milliAmps or greater in the current during normal operation, so that when current fluxuations drop below 200 milliAmps, air is identified, and the system shuts down. Alternatively, current fluxuations in the range of, for example, 50 milliAmps to 75 milliAmps can be used to identify that air is in the system. Additionally, an increase in the current or current fluxuations can indicate the presence of clot or thrombus within the high pressure lumen **536**. For example, a current of greater than 600 milliAmps can indicate that thrombus is partially or completely blocking the high pressure lumen **536**, or even the aspiration lumen **538**.

[0199] A vacuum line **556**, connected to the vacuum source **522**, can be connected to a negative pressure sensor **558**. If the vacuum or negative pressure of the or negative pressure source **522** is low or if a leak is detected in the vacuum line **556**, the control board **550** disables the pump **526** until the problem is corrected. The negative pressure sensor **558** can also be part of a safety circuit **560** that will not allow the pump **526** to run if a vacuum is not present. Thereby a comprehensive safety system **562**, including the safety circuit **560**, the pressure sensor **564** and/or the optical device **566**, and the negative pressure sensor **558**, requires both pump pressure and vacuum or negative pressure for the system to run. If a problem exists (for example, if there is either a unacceptably low pump pressure or an absence of significant vacuum or negative pressure), the control board **550** will not allow the user to operate the aspiration system **510** until all problems are corrected. This will keep air from being injected into a patient, and will assure that the aspiration system **510** is not operated at incorrect parameters.

[0200] FIG. 17 is a diagrammatic view of the distal end portion **568** of the assisted catheter aspiration system **510**, showing more details of the catheter **516**. The catheter **516** is a single-operator exchange catheter and includes a short guidewire lumen **534** attached to the distal end of the device. The guidewire lumen **534** can be between about 1 and about 30 cm in length, or between about 5 and about 25 cm in length, or between about 5 and about 20 cm in length, or approximately 13.5 cm in length. An aspiration lumen **538** includes a distal opening **540** which allows a vacuum or negative pressure (for example, from vacuum source **522**) to draw thrombotic material into the aspiration lumen **538**. A high pressure lumen **536** includes a distal orifice **542** that is set proximally of distal opening **540** by a set amount. For example, distal orifice **42** can be set proximally of distal opening **540** by about 0.0508 cm (0.020 inches), or by 0.0508 cm±0.00762 cm (0.020 inches±0.003 inches) or by another desired amount. The orifice **542** is configured to

spray across the aspiration lumen to macerate and/or dilute the thrombotic material for transport to vacuum source 522, for example, by lowering the effective viscosity of the thrombotic material. The axial placement of the fluid orifice 542 is such that the spray pattern interaction with the opposing lumen wall produces a spray mist and not a swirl pattern that could force embolic material out from the distal opening 540. The system can be configured so that the irrigation fluid leaves the pump at a pressure of between about 3,447,378 pascal (500 psi) and about 10,342,135 pascal (1500 psi). In some embodiments, after a pressure head loss along the high pressure lumen 536, the irrigation fluid leaves orifice 542 at between about 4,136,854 pascal (600 psi) and about 8,273,708 pascal (1200 psi), or between about 4,481,592 pascal (650 psi) and about 5,860,543 pascal (850 psi). In some cases, it can be possible (and even desired) to use the assisted catheter aspiration system 510 without operating the pump 526, and thus use the catheter 516 while providing, for example, a hand saline injection via a syringe. Or, in some cases, the assisted catheter aspiration system 510 can be used without the pump 526 attached, with the saline injections done by hand using a syringe through the high pressure lumen 536. If a clog occurs, the syringe can be removed and the pump 526 attached and initiated, for example, for the purpose of unclogging the high pressure lumen 536.

**[0201]** When normal blood flow is achieved after unblocking occlusions or blockages from atherosclerotic lesions and/or thrombosis, there is sometimes a risk of reperfusion injury. This can be particularly significant following thrombectomy of vessels feeding the brain for treatment of thromboembolic stroke, or following thrombectomy of coronary vessels feeding the myocardium. In the case of the revascularization of myocardium following a coronary intervention (e.g. thrombectomy). Reperfusion injury and microvascular dysfunction can be mechanisms that limit significant or full recovery of revascularized myocardium. The sudden reperfusion of a section of myocardium that had previously been underperfused can trigger a range of physiological processes that stun or damage the myocardium. Distal coronary emboli, such as small portions of thrombus, platelets and atheroma, can also play a part. Controlled preconditioning of the myocardium at risk has been proposed to limit the effect of reperfusion injury and microvascular dysfunction. The embodiments of the thrombectomy systems 100, 300 presented herein can be combined with additional features aimed at allowing flow control, in order to limit the potential dangers due to reperfusion following thrombectomy.

**[0202]** FIG. 18 illustrates a multi-purpose system 1200 comprising a multi-purpose catheter 1202 having an infusion/injection port 1204 and an aspiration port 1206. The infusion/injection port 1204 and the aspiration port 1206 can each comprise luer connectors, such as female luer lock connectors. A tubing set 1208 and a pressure sensor 1210 are connected in line with a vacuum source 1212. A cable 1214 carries signals from the pressure sensor 1210 to an aspiration monitoring system 1216 (FIG. 19), and connects to the aspiration monitoring system 1216 via an interface 1218, or plug, which is configured to connect to a port 1220 of a console 1222 of the aspiration monitoring system 1216. Apparatus and methods described herein can be used to monitor aspiration using the aspiration monitoring system 1216. In one manner of use, a syringe 1224 (FIG. 18) can be used to manually inject through the injection port 1204 and injection lumen 1225 (e.g., high pressure lumen) of the multi-purpose catheter 1202. The syringe 1224 can have an

injectable volume of about 5 ml or less, or in some embodiments about 1 ml or less. The injection lumen 1225 in some embodiments can be configured for injection of saline at a relatively high pressure, or at either high or low pressures. If the valve 1226 (e.g., stopcock) is closed, blocking the vacuum source 1212 from applying a vacuum or negative pressure to the aspiration lumen 1227 via the aspiration port 1206, then injection through the injection lumen 1225 causes injectate to be delivered to a site in the blood vessel near the distal exit of the injection lumen 1225 (at the distal end of the multi-purpose catheter 1202). Or, if the vacuum source 1212 is removed from, or simply not coupled to, the aspiration lumen 1227, then injection through the injection lumen 1225 can also cause injectate to be delivered to a site in the blood vessel near the distal exit of the injection lumen 1225. Either of these techniques can be utilized to apply a medicant to a blood vessel wall, or to an atherosclerotic plaque, or to a thrombus. In some cases, a clot busting drug (tissue plasminogen activator-tPA, thrombokinase, urokinase, thrombin, plasmin) is infused into a clot or thrombus, allowing it to act over a period of time. One purpose can be to soften the thrombus over time. Lytics, glycoprotein inhibitors (GPIs), vasodilators, and other drugs can be used to dilate the blood vessel, or treat disease in the area. The controlled, precision, local delivery allows an efficient use of the drug, with the desired amount delivered to the tissue to be treated with minimal runoff or waste. As many of these drugs are quite expensive, this efficiency reduces procedural costs. Because of the precision diameter of the injection lumen 1225, and its known length, the injection lumen 1225 contains a known volume, or dead space. This additionally allows a known, controlled, precision injection of medicant. A representative injection lumen 1225 can have a length of 150 cm and have an inner diameter of 0.038 cm (0.015 inches), and thus a total volume of only 0.17 ml. The injection lumen 1225 volume can be varied, by controlling the diameter of the inner diameter of the injection lumen 1225 and/or the length of the injection lumen 1225. For example, the injection lumen 1225 volume can be between about 0.08 ml and about 0.26 ml, or between about 0.14 ml and about 0.20 ml. By injecting through the injection lumen 1225 with a small bore syringe (e.g., 1 ml) or with a precision pump, an accurate measurement of the medicant delivered can be made. If, however, the valve 1226, or stopcock, is opened, connecting the vacuum source 1212 to the aspiration port 1206 and applying a vacuum or negative pressure on the aspiration lumen 1227, a forced aspiration is commenced, as described herein. As described, the injection lumen 1225 can serve either a closed system (aspiration) or an open system (injection of infusate). At the beginning of a procedure, it is not always known what different actions will be required, thus the use of the multi-purpose catheter 1202 and multi-purpose system 1200 can eliminate the need to use multiple catheters (e.g., both a microcatheter and a single function aspiration catheter).

**[0203]** FIGS. 20-24 illustrate a multi-purpose system 1240 comprising a multi-purpose catheter 1242 having an infusion/injection port 1244 and an aspiration port 1246. Cooled saline can be injected from a saline bag 1248 (FIG. 23) through a tubing set 1250, attached to the saline bag 1248 via a spike 1252. A pump 1254 (FIG. 24), which can include a displacement pump, such as a piston pump, includes an interface 1256 for attaching a cassette 1258 (FIG. 20). In some embodiments, the pump 1254 has moving portions that connect to a moving piston 1255 in the cassette 1258 to inject controlled amounts of fluid. As described in relation to the multi-purpose system 1200 of FIG. 18, the injection can

serve either a closed system (aspiration) or an open system (injection of infusate), depending on whether a valve **1260** which couples a vacuum source **1262** to the aspiration port **1246** via extension tubing **1264** is open or closed, or simply whether the vacuum source **1262** is attached or not attached. A pressure sensor **1266** communicates with the interior of the extension tubing **1264**, but can communicate with the interior of other parts of the flow path. A cable **1268** carries signals from the pressure sensor **1266** to an aspiration monitoring system **1270** (FIG. 22), and connects to the aspiration monitoring system **1270** via an interface **1272**, or plug, which is configured to connect to a port **1274** of a console **1276** of the aspiration monitoring system **1270**. The utility of the multi-purpose systems **1200**, **1240** in multiple modes is facilitated by the sterile fluid path combined with precision volume control (either by small syringe **1224**, or by the precision pump **1254**). In addition, the aspiration monitoring system **1216**, **1270** allows real-time feedback to the user, further facilitating controlled delivery and/or aspiration.

**[0204]** The multipurpose system **1200**, **1240** optimizes interventional procedures, such as percutaneous coronary interventions (PCIs), for simplicity, ease of use, and cost. Infusing drugs intracoronary prepares clot for aspiration by placing highly concentrated pharmacological agents directly at the lesion site, at a location which can be more distal (e.g., more superselective) than that which is typically accessible by the tip of a guiding catheter. This can minimize the volume of drug/medicant/agent used. By limiting the amount of certain medicants, systemic complications (bleeding, etc.) can be minimized or eliminated. The direct application of the medicant, for example at the thrombus itself, allows it to soften or disaggregate the thrombus. The maceration of the thrombus, for example by a saline jet **1278** (FIG. 21) injected through the injection lumen **1257** of the multi-purpose catheter **1242**, keeps the catheter aspiration lumen **1259** patent at all times without interruption, and allows standardized catheter advancement technique, for example, moving the catheter slowly from a proximal location to a distal location in the vessel (in relation to the thrombus). The maceration also dilutes the proximally flowing aspirate for optimal aspiration efficiency. In certain situations, aspiration can be performed until the normal blood flow is restored (at least to a significant level), and then the vacuum source **1262** can be closed off via the valve **1260** and cooled injectate can be infused into the blood vessel. The resultant selective cooling of this area serves to reduce reperfusion injury by potentially slowing ischemic cell metabolism. The injection of cooled infusate can be used any time post-aspiration, pre-stenting, without having to remove an aspiration device, advance a new injection device. Because the multi-purpose catheter **1202**, **1242** is already in place, this critical operation can be started immediately. By having these functionalities all on one catheter, there is also a cost saving to the user.

**[0205]** In aspiration mode, the aspiration monitoring system **1216**, **1270** is able to monitor proper function of the aspiration circuit at all times. The user knows when warnings are communicated or when the system (e.g., motor) shuts down, that a key event has occurred, an event that needs attending. This knowledge helps the user avoid plunging the catheter distally, potentially causing distal embolism. In infusion/infusate cooling mode, the pump **1254** pumps at a predetermined constant volume or speed to deliver constant temperature cooling infusate. Core temperature feedback (e.g., via rectal, esophageal, ear or other temperature probes) can be used to indicate to the system that further cooling must stop. For example, a core body temperature

below 35° C. or below 34° C. The feedback of a temperature below the threshold can be used to shut down the pump and/or to send a warning. The infusate path, which is precision and direct to the catheter tip and/or ischemic area, results in concentrated cooling, causing the least systemic hypothermic potential. By bypassing the aspiration lumen (e.g., with the valve **1260** closed), unintentional embolic debris is less likely to be infused back into the blood vessel, and less likely to thus be sent downstream to critical areas. This eliminates the need to exchange devices after flow has been restored.

**[0206]** In some cases, in infusion mode, infusate is injected into the fluid injection lumen **1225**, **1257** with a relatively low pressure. In some cases, maceration is performed at a relatively high pressure. In some cases, the multi-purpose system **1240** can be used without the pump **1254** attached, with the saline injections done by hand using a syringe attached to the infusion/injection port **1244**. If a clog occurs, the syringe can be removed and the pump **1254** attached and initiated, for example, for the purpose of unclogging the injection lumen **1257**. In an exemplary procedure, a user places a catheter similar to the multi-purpose catheter **1202** of FIG. 18 or multi-purpose catheter **1242** of FIGS. 20-21 in the vasculature. Initially, the user can choose to have neither a pump **1254**, nor a syringe **1224** (FIG. 18) attached to the multi-purpose catheter **1202**, **1242**. The user can then commence aspiration through the aspiration lumen **1227**, **1259** via a vacuum source **1212**, **1262**, thus utilizing the multi-purpose catheter **1202**, **1242** as a simple (vacuum or negative pressure only) aspiration catheter. If at any time, the user determines that additional positive pressure injection of saline and/or medicant is needed, for example, to overcome clogging, overcome slow aspiration, or to increase maceration or dilution of the thrombus, the user can attach the pump **1254** or the syringe **1224** to the infusion/injection port **1204**, **1244** and begin injecting the saline and/or medicant.

**[0207]** In one embodiment, an aspiration system includes an elongate catheter having a proximal end and a distal end, the catheter including an aspiration lumen having a proximal end and a distal end and a high pressure injection lumen having a proximal end and a distal end and extending from a proximal end of the catheter to a location adjacent a distal end of the aspiration lumen, and at least one orifice at or near the distal end of the high pressure injection lumen and configured to allow high pressure liquid injected through the high pressure injection lumen to be released into the aspiration lumen, wherein the proximal end of the high pressure injection lumen is configured to be repeatedly coupled to and uncoupled from one or more injection modules. In some embodiments, the one or more injection modules include a first injection module and a second injection module. In some embodiments, the first injection module comprises a pump and the second injection module comprises a syringe. In some embodiments, the second injection module comprises a syringe having a volume of about 5 ml or less. In some embodiments, the second injection module comprises a syringe having a volume of about 1 ml or less. In some embodiments, the second injection module comprises a syringe containing a drug.

**[0208]** FIGS. 25 through 33 illustrate several different embodiments of devices having a pressure sensor **1300**, which is configured to function as a component in an aspiration monitoring system sharing some or all of the functionality of any one of the aspiration monitoring systems **48**, **62**, **78**, **900**, **1216**, **1270** presented herein. FIG. 25 illustrates an aspiration catheter **1302** having a distal end

**1304** and a proximal end **1306**, the proximal end **1306** comprising a female luer connector **1308**. The pressure sensor **1300** is in fluid communication with (e.g., fluidly coupled to) a lumen of the aspiration catheter **1302**. FIG. 26 illustrates a tubing set **1310** having a male luer **1312** and a female luer **1314**, extension tubing **1316**, and a stopcock **1318**. The pressure sensor **1300** is in fluid communication with a lumen of the extension tubing **1316**. FIG. 27 illustrates a stopcock **1320** having a male luer **1322**, a female luer **1324**, and a valve **1326**, the valve **1326** located proximally of the pressure sensor **1300**. The pressure sensor **1300** is in fluid communication with an internal cavity of the stopcock **1320**. FIG. 28 illustrates a stopcock **1328** having a male luer **1330**, a female luer **1332**, and a valve **1334**, the valve **1334** located distally of the pressure sensor **1300**. The pressure sensor **1300** is in fluid communication with an internal cavity of the stopcock **1328**. FIG. 29 illustrates a syringe **1336** having a male luer **1342**, a barrel **1338**, and a plunger **1340**. The syringe **1336** can include a locking feature **1344**, which allows the plunger **1340** to be locked in relation to the barrel **1338**, such as a VacLok® syringe. The pressure sensor **1300** is located distally of the barrel **1338** and is in fluid communication with an internal cavity of the barrel **1338**.

[0209] FIG. 30 illustrates a syringe **1346** having a male luer **1352** (i.e., luer connector, luer lock), a barrel **1348**, and a plunger **1350**. The syringe **1346** can include a locking feature **1344**. The pressure sensor **1300** is in fluid communication with an internal cavity of the barrel **1348**, and can be directly connected to either the barrel **1348** or the male luer **1352**, or a hollow transition **1351** between them. FIG. 31 illustrates an aspiration system **1354** comprising a syringe **1356** having a male luer **1357**, a barrel **1358** and a plunger **1360**. The syringe **1356** can include a locking feature **1344**. The aspiration system **1354** also comprises a connector assembly **1361** comprising a male luer **1362**, a valve **1364**, and a female luer **1365** (connected under the male luer **1357** in FIG. 31). The pressure sensor **1300** is in fluid communication with an internal lumen or cavity between the barrel **1358** of the syringe **1356** and the male luer **1362** of the connector assembly **1361**. FIG. 32 illustrates an aspiration system **1366** comprising a syringe **1368** having a male luer **1369**, a barrel **1370** and a plunger **1372**. The syringe **1368** can include a locking feature **1344**. The aspiration system **1366** also comprises a connector assembly **1373** comprising a male luer **1374**, a valve **1376**, and a female luer **1377** (connected under the male luer **1369** in FIG. 32). The pressure sensor **1300** is in fluid communication with an internal lumen or cavity between the barrel **1370** of the syringe **1368** and the male luer **1374** of the connector assembly **1373**. FIG. 33 illustrates an aspiration system **1378** comprising a syringe **1380** having a male luer **1382**, a barrel **1384** and a plunger **1386**. The syringe **1380** can include a locking feature **1344**. The aspiration system **1378** further comprises a tubing set **1388** having a male luer **1390** and a female luer **1392**. A valve **1394** is located either proximal or distal to the pressure sensor **1300**. Extension tubing **1396** can be utilized to connect one or more of the components of the tubing set **1388**, but in some cases, the components can be connected directly. The pressure sensor **1300** is in fluid communication with an internal lumen of the tubing set **1388**. The stopcock or valve in any of these embodiments can be a one-way stopcock or a three-way stopcock or a one-way valve or a three-way valve. Other embodiments can exist which combine one or more elements of each of the embodiments presented herein. These embodiments are also included within the scope of this disclosure. In any of the embodiments in which a male luer is used, it can be replaced

with a female luer or another liquid-tight connector. In any of the embodiments in which a female luer is used, it can be replaced with a male luer or another liquid-tight connector. As such, either of the connector assemblies **1361**, **1373** can be connected in reverse manner to the syringes **1356**, **1368**, i.e., wherein the distal end becomes the proximal end and is thus connected to the syringe **1356**, **1368**, and wherein the proximal end becomes the distal end.

[0210] FIG. 34 illustrates a thrombectomy system **300** which incorporates the high pressure injection of a liquid, for example sterile saline solution, in order to macerate and aspirate thrombus **104**. A guiding catheter **108** has an inner lumen **110** extending between a proximal end **144** and a distal end **120**. A y-connector **148**, coupled to the proximal end **144** of the guiding catheter **108**, includes a proximal seal **150** and a sideport **152** and is configured to couple the inner lumen **110** of the guiding catheter **108** to a vacuum source **146**, as described in relation to the prior embodiments. A thrombectomy catheter **306** comprises a distal tube **314** having a distal end **316** and a proximal end **318**, the proximal end **318** incorporating one or more sealing members **324** for sealing off an annulus **342** between the guiding catheter **108** and the distal tube **314**, as described in relation to the prior embodiments. The distal tube **314** has an aspiration lumen **330**. A support/supply tube **368**, having a lumen **370**, is coupled to the distal tube **314**. The support/supply tube **368** serves as a support member for pushing and pulling the thrombectomy catheter **306**, but is also a conduit (via the lumen **370**) for high pressure saline, which is injected from the proximal end **372** to the distal end **374**. The saline is supplied from a saline source **376** (e.g., saline bag, bottle) and pressurized by a pump **378**, through a supply tube **380** and through a luer connector **382** which is connected to a luer hub **384** coupled to the support/supply tube **368**. In some embodiments, the support/supply tube **368** comprises a hypo tube. In some embodiments, the support/supply tube **368** comprises stainless steel or nitinol. The distal end **316** of the distal tube **314** can include a skive **358**, which aids in the trackability of the distal tube **314** through vasculature of a patient. In some embodiments, the inner diameter of the aspiration lumen **330** of the distal tube **314** can be approximately one French size smaller than the inner diameter of the inner lumen **110** of the guiding catheter **108**. In some embodiments, the thrombectomy catheter **306** can include a support tube or support shaft to replace the support/supply tube, and not comprise a lumen **370**. Thus, aspiration is only controlled by evacuation of the inner lumen **110** of the guiding catheter **108** in combination of the aspiration lumen **330** of the distal tube **314**, and injection of a high pressure liquid is not necessary. Other embodiments of the thrombectomy catheter **306** are described in U.S. Pat. No. 9,433,427, issued Sep. 6, 2016, and entitled “Systems and Methods for Management of Thrombosis,” which is hereby incorporated by reference in its entirety for all purposes

[0211] FIG. 35 illustrates the proximal end of a guiding catheter **108** used with aspiration catheters, such as the thrombectomy catheter **306** of FIG. 34. A hemostasis valve **389** of y-connector **390** seals over both the support/supply tube **391** and the guidewire **28**. The hemostasis valve **389** (e.g., Touhy-Borst, longitudinally spring-loaded seal, etc.) must be adjusted to allow catheter and/or guidewire **28** movement (translation, rotation), but must keep air from being pulled into the lumens during aspiration. Because of the continual adjustment often required to the hemostasis valve **389**, for example, to aid movement of the catheter and/or guidewire, the hemostasis valve **389** can create significant variability in the amount of air that can leak. A

leak (e.g., at location 393) can be fast, and can be unknown to the user. A pressure sensor 394 used in conjunction with any of the aspiration monitoring systems described herein allows the user to know immediately if the seal of the hemostasis valve 389 of the y-connector 390 is not correctly sealed. Additionally, any leaks between the distal luer 388 of the y-connector 390 and the luer hub 386 of the guiding catheter 108 can be detected by the aspiration monitoring system. Furthermore, any leaks between a luer 392 of the pressure sensor 394 and a sideport 395 of the y-connector 390 or between a luer connector 396 of the extension tube 387 and a luer fitting 397 of the pressure sensor 394 can be detected by the aspiration monitoring system. The aspiration monitoring system can be configured to be integral or attachable to any component of the aspiration circuit (e.g., aspiration catheter, syringe/vacuum source), or can be connected in series (at any point) between these components. In some embodiment, the aspiration monitoring system can comprise a flow or pressure sensor or detector that is in series or in parallel with the components, or is configured to be placed in series or in parallel with the components. In any of these configurations, a number of different leak locations can be assessed by the aspiration monitoring system of the embodiments disclosed herein. The aspiration monitoring system can be configured to detect: changes, relative changes, absolute changes, thresholds, absolute values, the presence of or the lack of pressure and/or flow. The aspiration monitoring system can be configured to determine the operation status of a system including a catheter having an aspiration lumen. In some cases, the aspiration monitoring system can be configured to provide information about the operation of the system that is not discernable from typical clues such as angiography, sound, feel, or other visual, auditory, tactile or other feedback from the system itself.

[0212] FIG. 36 illustrates an aspiration system 1400 comprising an aspiration catheter 1402 comprising an elongate shaft 1401 including an aspiration lumen 1404 having an open distal end 1405 and a proximal end 1406 configured to couple to a peristaltic pump 1408. The peristaltic pump 1408 can be a roller pump having a base 1426, a pressure shoe 1428 carried by the base 1426, and a rotatable head 1430, rotatably coupled to the base 1426, and carrying two or more rollers 1432a-d. The rollers 1432a-d are arrayed around a perimeter 1434 of the rotatable head 1430. The rotatable head 1430 is configured to be rotatable in at least a first rotational direction 1436 with respect to a rotational axis 1499. The rotatable head 1430 can be rotated by a motor 1497, either directly, or with a gear train 1495. The peristaltic pump 1408 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 1408 can alternatively, or additionally be powered by a power cord 1493 configured to connect to a power supply. An extension tube 1438 having a distal end 1440 and a proximal end 1442, and having a lumen 1444 extending therethrough, is hydraulically coupled to the proximal end 1406 of the aspiration lumen 1404 via a connector 1424. The extension tube 1438 can be supplied (e.g., sterile) with the aspiration catheter 1402, or can be packaged and supplied separately. A Touhy-Borst seal 1446 carried on the connector 1424 is configured to be loosened/opened to allow the insertion of a guidewire 1448 through the connector 1424 and the aspiration lumen 1404. The aspiration lumen 1404 can thus be used to track the aspiration catheter 1402 over the guidewire 1448 through a subject's vasculature. The Touhy-Borst 1446 can be tightened to seal over the guidewire 1448, to maintain hemostasis. Other types of seals can be incorporated in place of the

Touhy-Borst 1446, including a spring-loaded, longitudinally compressible and actuatable seal. The extension tube 1438 includes a male luer 1450 at its distal end 1440, for connecting to a female luer 1452 of the connector 1424. The male luer 1450 can include a stopcock 1454, which is configured to be turned to select between an open position (shown) or a closed position. The extension tube 1438 and its components can be supplied sterile as a single unit. Alternatively, the extension tube 1438 can be integral with the aspiration lumen 1404, or can be permanently attached to the connector 1424. In use, a compressible portion 1437 of the extension tube 1438 is placed within the pressure shoe 1428 of the peristaltic pump 1408 such that rotation of the rotatable head 1430 in the rotational direction 1436 causes fluid to be forced through the lumen 1444 of the extension tube 1438 from the distal end 1440 to the proximal end 1442, via compression of the compressible portion 1437 by the rollers 1432, one at a time. The single insertion step to couple the compressible portion 1437 to the peristaltic pump 1408 is simple, quick, reliable, and does not involve any connection that has to seal (e.g., luer, etc.). It is also easier to visualize whether a peristaltic pump is successfully operating, vs. a vacuum pump or evacuated syringe. This may be because, under relatively high vacuum or negative pressure conditions, blood tends to cavitate, thus filling the space of a container (e.g., canister or syringe) at an accelerated rate due to the excess gaseous volume. The gaseous bubbles may also make it more difficult to see inside and visually inspect the condition. Optionally, an interface 1456 on the peristaltic pump 1408 is configured to allow a user to input information or commands to the peristaltic pump 1408 or other components of the system 1400. Otherwise, hardware or firmware can be pre-programmed with specific run parameters (motor speed, rotation speed, etc.). In some embodiments, there are only two rollers 1432. In other embodiments, there are three rollers 1432. In still other embodiments, as shown, there are four rollers 1432. In an alternative embodiment, instead of rollers, smooth, radiused bumps of a rigid material slide over the compressible portion 1437, compressing it. In this alternative embodiment, the compressible portion 1437 and/or the bumps can be treated with a lubricious material or can be constructed from significantly lubricious materials to lower the sliding friction between the compressible portion 1437 and the bumps. Returning to the embodiment of FIG. 36, the compressible portion 1437 can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible section 1437 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 1438, or in other embodiments, can comprise the entirety of the extension tube 1438 between the distal end 1440 and the proximal end 1442. The proximal end 1442 of the extension tube 1438 can be coupled to a hub 1457 of a canister 1458 having an interior 1460, to allow fluid 1459 passing through the extension tube 1438 to pass into the interior 1460. An additional hub 1462 in the canister 1458 can be left open (as shown) to allow the unfilled interior 1460 to match atmospheric pressure. Alternatively, the canister 1458 can be replaced by another type of receptacle, such as a bag, or more specifically an empty infusion bag, configured for collecting aspirate therein.

[0213] The aspiration catheter 1402 additionally has a high pressure injection lumen 1410 for injecting saline from a fluid source 1479, for example, via a high pressure pump 1412. A tubing set 1464 can include a pump cartridge 1466 having a piston, or bellows, or other movable element that the pump 1412 can manipulate using an internal motor 1491,

thus pressurizing saline (or other fluid) from the fluid source 1479 with a significantly high pressure such that the saline is forced through the injection lumen 1410 of the aspiration catheter 1402. The tubing set 1464 includes proximal end 1468 having a spike 1489, or other connecting element, for hydraulically coupling the tubing set 1464 to the fluid source 1479. The tubing set 1464 further has a distal end 1470, which can comprise a male luer, and which is configured to hydraulically couple the tubing set 1464 to the injection lumen 1410 via a female luer 1472. The tubing set 1464 can be supplied sterile as a single unit, or alternatively can be permanently attached to the aspiration catheter 1402. In use, injected saline is forced through the injection lumen 1410 by the pump 1412 and exits an orifice 1474 at a distal end 1476 of the injection lumen 1410. The injection lumen 1410 can extend within a separate tube 1478 (injection tube) that is substantially or entirely within the shaft 1401. In some embodiments, the tube 1478 is attached to the internal wall of the shaft 1401 only at a distal end portion 1403. Thus, the free-floating nature of the remainder of the tube 1478 within the aspiration lumen 1404 increases the flexibility and trackability of the shaft 1401. There also a reduced chance of the tube 1478 being kinked because of flexing of the shaft 1401, because the bending of the shaft 1401 is not directly applied to the tube 1478. The high pressure saline is forced through the injection tube 1478 and out the orifice 1474, causing a jet 1487. The jet 1487 is within the aspiration lumen 1404, just proximal the open distal end 1405 which can create a Venturi effect that forces blood or thrombus that is external and adjacent the open distal end 1405 into the aspiration lumen 1404. The operation of the peristaltic pump 1408 with the rotatable head 1430 rotating in the first rotational direction 1436 moves fluid and thrombus from the open distal end 1405 of the aspiration lumen 1404 to the proximal end 1442 of the extension tube 1438 by continually and forceably moving the fluid column within the lumen 1444 of the extension tube 1438, which pulls the fluid column within the aspiration lumen 1404 along with it. The combination of the operation of the peristaltic pump 1408 and the jet 1487 created by the high pressure saline cause the maceration of thrombus, and the movement/flow of material (saline/blood/macerated thrombus/small pieces of thrombus) through the aspiration lumen 1404 from the open distal end 1405 to the proximal end 1406, through the interior 1485 of the connector 1424, and through the lumen 1444 of the extension tube 1438 from its distal end 1440 to its proximal end 1442, and finally into the interior 1460 of the canister 1458. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system 1400. Blood vessels can include peripheral blood vessels, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

[0214] An aspiration monitoring system 1414 comprising a pressure transducer 1416 can be coupled, for example, between the distal end 1440 of the extension tube 1438 and the connector 1424 and/or the proximal end 1406 of the aspiration lumen 1404 of the aspiration catheter 1402. The aspiration monitoring system 1414 can include any of the features described in relation to the other aspiration monitoring systems 48, 62, 78, 900, 1216, 1270 disclosed herein. Signals from the pressure transducer 1416 are carried on an electric cable 1480 to an input 1482 of the pump 1412. A controller 1484 within the pump 1412 is configured to control the operation of the pump 1412, including motor 1491, but the controller 1484 can also be configured to control the operation of the peristaltic pump 1408, via a

cable 1486, or wirelessly. The controller 1484 can comprise a microcontroller. The controller 1484 can alternatively be located within the peristaltic pump 1408, or can be located at another location. Control using signals of measured pressure from the pressure transducer 1416 adds an additional safety element to the system 1400. Furthermore, a non-functional system 1400 or particular component of the system 1400 can be quickly identified. For example, a leak, incomplete connection, incomplete priming of one of the lumens, rupture, or breakage can cause changes in the signal from the pressure transducer 1416, thus allowing their identification. Unallowably high pressures can also be quickly identified, and the controller 1484 is configured to automatically shut down the pump 1412, thus protecting the motor 1491 of the pump 1412 from burnout or overheating, and the failure or danger associated therewith. The peristaltic pump 1408 can also be shut down by the controller 1484. In some embodiments, the peristaltic pump 1408 is configured to be shut down by the controller 1484 after the pump 1412 is shut down (e.g., after a finite delay). The delay can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. The integrity of the tube 1478 is also protected, e.g., avoiding unnaturally high pressures that could lead to burst. In some embodiments, the peristaltic pump 1408 can be battery powered, and the controller 1484 can be located within the peristaltic pump 1408, thus providing a self-contained peristaltic pump 1408 which can be easily moved from one location to another. In some embodiments, the peristaltic pump 1408 can even be easily cleanable and sterilizable, such that it can be placed within a sterile field, such as a sterile field in the vicinity of a patient. In some embodiments, the pump 1412 is configured to remain in a non-sterile area, while the peristaltic pump 1408 is configured for sterile use. A push button 1411 can be carried on the peristaltic pump 1408, and can be configured for activation by a user, for example, a user who is scrubbed for contact of sterile articles only. The push button 1411 can be configured to start or stop the operation of the peristaltic pump 1408. Additionally, the push button can be configured to start or stop the operation of the pump 1412 (e.g., via the cable 1486). In some embodiments, the peristaltic pump 1408 and the pump 1412 are combined into a single console. This allows for a smaller size that can be mounted on a standard IV pole.

[0215] In some embodiments, activation of the push button 1411 by a finger of a user starts the operation of the peristaltic pump 1408, and then starts the operation of the pump 1412, with a slight delay after the peristaltic pump 1408 is started. The delay is useful to assure that some aspiration, or a significant amount of aspiration, is being applied to the aspiration lumen 1404 prior to the injection of pressurized fluid (e.g., saline) through the injection lumen 1410. Thus, blood vessels or other vasculature in the vicinity of the open distal end 1405 are spared any injection of fluid from a high pressure jet, as it is instead aspirated through the aspiration lumen 1404, along with any aspirated thrombus or blood. In addition, in some embodiments, activation of the push button 1411 by a finger of a user during the operation of the pump 1412 and the peristaltic pump 1408 stops the operation of the pump 1412 and the operation of the peristaltic pump 1408 at the same time. In other embodiments, a delay can be applied, for example, such that the pump 1412 is stopped, and then the peristaltic pump 1408 is stopped slightly afterwards. The length of the delays described can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. In some

embodiments, the controller 1484 is configured to change the rotational speed of the rotatable head 1430 of the peristaltic pump 1408, for example, increase the speed or decrease the speed. In some embodiments, the controller 1484 is configured to change the flow rate (injection rate) of the pump 1412, for example, increase the injection rate or decrease the injection rate. In some embodiments, the controller 1484 is configured to change the speed/rate of both pumps 1408, 1412 at the same time. In some embodiments, the controller 1484 is configured to change the speed/rate of one of the pumps 1408, 1412 and then change the speed/rate of the other of the pumps 1408, 1412 after a particular delay. Any of these commands from the controller 1484 can be in response to changes in the signal received from the pressure transducer 1416. The peristaltic pump 1408 in its peak pulse (e.g., sinusoidal peak amplitude) provides a significant negative pressure gradient such that the difference between a clog state pressure transducer 1416 reading and a free flow state pressure transducer 1416 reading is amplified. Thus, a larger number of potential thromboembolic events are avoided, such as thrombus being release from the open distal end 1405 of the aspiration lumen 1404 of the aspiration catheter 1402. The pressure variations on the pressure transducer 1416 tend to be significantly greater when using a peristaltic pump 1408 than when using a vacuum pump, or other vacuum source (e.g., evacuated syringe). One significant advantage is that the user can be made clearly aware when clot/thrombus is not being aspirated, and thus, when aspiration is free flow, causing loss of blood without removal of thrombus 1402. It is much easier to be aware of the status at the open distal end 1405 of the aspiration catheter. Current vacuum pumps do not have a similar clear-cut manner of demonstrating active vs. resting states. The user is thus notified, and the pumps 1408, 1412 are stopped to minimize blood loss, and to allow repositioning onto thrombus. Peristaltic pumps 1408 also tend to be less noisy than vacuum pumps, and less likely to disturb communication of medical personnel during a procedure, or increase stress.

[0216] Stopping the peristaltic pump 1408 leaves at least one roller 1432 in a position compressing the compressible portion 1437 of the extension tube 1438. Thus, an open/close valve or pinch valve, or stopcock, or other valve is not needed. The fact that the rotatable head 1430 is already moving means that roller 1432 moves to the occluding position rapidly, without a large inertial requirement, when the peristaltic pump 1408 is stopped. This can thus be faster than the activation of standard electrically-activated pinch valves, which are initially motionless and need to be placed into motion prior to pinching. The motor 1497 can comprise a stepper motor that is directed (e.g., by the controller 1484) such that the rotatable head directs one of the rollers 1432 to occlude the lumen 1444 of the extension tube 1438 at the compressible portion 1437. In FIG. 36, the roller 1432c is in position (if the motor 1497 were stopped) to occlude the lumen 1444. Thus, the peristaltic pump 1408 itself can inherently minimize the potential of distal embolization, as stoppage of pump immediately or almost immediately creates stasis. Alternatively, a non-stepper motor, such as a brushless DC motor, can be utilized along with an encoder (e.g., optical encoder), or another type of position sensor, in place of a stepper motor. Additionally, unmacerated clot can thus be stopped from entering the aspiration lumen 1404. As discussed, in other embodiments, the rollers 1432 can be replaced by non-rotating bumps or protrusions, that slide over the compressible portion 1437 of the extension tube 1438, instead of rolling over. In some embodiments, the bumps/protrusions and/or the external surface of the com-

pressible portion 1437 can be coated with a silicone, hydrophilic, or other lubricious material to lower the friction.

[0217] The controller 1484 can be configured to control the operation of the pump 1412 to cause the pump 1412 to inject pressurized fluid in a pulsatile manner. The high pressure jet is applied in a pulsatile fashion to optimize the cutting ability of the jet on a piece of thrombus. For example, a portion of thrombus that is aspirated into the open distal end 1405 of the aspiration lumen 1404 of the aspiration catheter 1402 can be more readily severed by a pulsating jet, much in the manner that a reciprocating saw. The controller 1484 is configured to operate the pump 1412 to pressurize fluid through the injection lumen such that the one or more jets are pulsatile. The controller 1484 is also configured to operate the peristaltic pump 1408 to further aid that that pressurized fluid injected through the injection lumen causes the one or more jets to be pulsatile. For example, the controller 1484 can send a signal to cause a sinusoidal variation in the speed of the motor 1491. The degree of pulsatility (pulse rate, peak pulse, pulse wave shape, rise time, on time, off time) can be tailored and controllably applied by the controller 1484 on the pump 1412 and/or the peristaltic pump 1408.

[0218] The use of a peristaltic pump 1408 assures that the interior of the aspiration lumen 1404 and lumen 1444 of the extension tube 1438, and its contents, are not contacted, thus further assuring maintenance of sterility. The use of a peristaltic pump 1408 also causes minimal or virtually no cavitation to blood being removed. If there were any cavitation during aspiration, proximal to the peristaltic pump 1408, after the blood and aspirate passes through the rollers 1432, the blood is exposed to atmospheric pressure, and the cavitation disappears. Thus, it is easier to judge the amount of blood that has been collected or is being collected into the canister 1458 for it is not obscured by bubbles or foam, such that an indicative volume of collected blood is clearly visible and reliable to measure. Additionally, it is easier to reuse the blood quickly, if, for example, it is to be reinjected into the subject. It is also safer and more reliable to infuse blood that does not have significant air bubbles. The use of a vacuum source such as a vacuum bottle or evacuated syringe can tend to create a larger amount of cavitation. Thus, the peristaltic pump 1408 can be used in order to provide an efficient procedure, and also to maximize the volume of blood that can be reinjected/reinfused. The tubing set 1464 separates the extension of the injection lumen 1410 from the aspiration lumen 1404 at the male luer 1410 of the connector 1424, thus only the compressible portion 1437 of the extension tube 1438 need be compressed by the rollers 1432. Other portions of the aspiration catheter 1402 are thus not compressed by the rollers 1432, and therefore are not in danger of being crushed or otherwise damaged. The distal end 1483 of the aspiration catheter 1402 can in some embodiments resemble that of the catheter 516 of FIG. 17. The aspiration catheter 1402 can in some embodiments be replaced by the thrombectomy system 300 of FIG. 34, or the other embodiments of the thrombectomy catheter 306 described in U.S. Pat. No. 9,433,427, issued Sep. 6, 2016, and entitled "Systems and Methods for Management of Thrombosis," which is hereby incorporated by reference in its entirety for all purposes. The use of the peristaltic pump 1408 has additional advantages in comparison to a vacuum pump. The peristaltic pump 1408 can be configured to be controlled by the controller 1484 such that it runs only when the pump 1412 is injecting. Thus, the noise is reduced in comparison to a system using a vacuum pump, as the vacuum pump is on (operating) the entire time.

[0219] FIG. 37 illustrates a subject 1500 in a hospital bed 1502 or table being injected with blood in three different modalities. During thrombectomy procedures, thrombus/clot is removed from the blood vessels of the subject 1500. In some instances, the blood volume of the patient becomes abnormally low, and fluids or blood need to be reinjected into the patient. In a first modality, the peristaltic pump 1408 of the system 1400 of FIG. 36 is shown. The aspiration catheter 1402 is inserted in the subject 1500 and the aspiration (thrombectomy) procedure is being performed. Instead of the canister 1458, the extension tube 1438 at its distal end 1442 is connected to a return conduit 1505 comprising an intravascular (IV) line 1504 which is inserted into a vein of the subject 1500. The blood is driven by the rollers 1432 of the peristaltic pump 1408 so that it passes through a blood filter 1506, which removes any residual thrombus or particulate prior to the blood being infused into the veins of the subject. Heparin, or other additives can also be added to the blood as it is being injected into the subject 1500 at port 1481, which communicates with the intravascular (IV) line 1504. As the blood only flows through a single sterile composite conduit, an efficient, cleanly reinfusion method is provided. The blood can be purified, for example, to remove red blood cells or portions of red blood cells that have undergone hemolysis. One such reinfusion device is the Haemonetics Cell Saver® Elite+ Autotransfusion System. It is believed that peristaltic pumps 1408 cause less damage to blood cells, and thus less cleaning can be needed, if any. Thus, a higher yield of blood after using the Cell Saver is possible because of the advantages of the peristaltic pump 1408. Also, the blood can be easily transferred to the Cell Saver in a non-contact manner, directly from the extension tube 1438, that is not possible in the transfer from a collection container used with a vacuum source. The blood can even be kept sterile upon being sent directly into the Cell Saver. In some embodiments, the extension tube 1438 can be significantly translucent, so that the thrombus can be assessed during aspiration. A video camera or magnifying element (low power microscope, etc.) can be focused on the extension tube 1438 to better identify the state of the thrombus being aspirated (quantity, amount of maceration). There can be an almost real-time feedback of the condition of the thrombus being removed from within the vasculature of the patient.

[0220] In a second modality, blood is collected in a prior procedure in the canister 1458 (FIG. 36). The blood can then be filtered, or even spun in a centrifuge to obtain particular components. Heparin, or other additives can also be added to the blood. The blood is then placed in a blood bag 1508 (or blood bottle) and infused into the vein of the subject 1500 using a passive drip through an IV line 1510 (e.g., via gravity alone). In other cases, a pressurizable bag 1512 can be used around the blood bag 1508 to increase the compression on the blood bag 1508, thus increasing the flow rate into the vein. In some cases, the blood can even be injected directly into the arterial system, for example, through an arterial line (a-line). The blood can additionally be purified as described above.

[0221] In a third modality, blood is collected in a prior procedure in the canister 1458 (FIG. 36). The blood can then be filtered, or even spun in a centrifuge to obtain particular components. Heparin, or other additives can also be added to the blood. The blood is then placed into a blood bag 1514, and pumped into a vein of the subject 1500 using an infusion pump 1516. Insertion points 1518a, 1518b, 1518c are shown for the first, second, and third modalities, respectively. The blood can additionally be purified as described above.

[0222] FIG. 38 illustrates an alternative aspiration system 1400' comprising an aspiration catheter 1402' comprising an elongate shaft 1401' including an aspiration lumen 1404' having an open distal end 1405' and a proximal end 1406' configured to couple to the peristaltic pump 1408. The peristaltic pump 1408 can be a roller pump having a base 1426, a pressure shoe 1428 carried by the base 1426, and a rotatable head 1430, rotatably coupled to the base 1426, and carrying two or more rollers 1432a-d. The rollers 1432a-d are arrayed around a perimeter 1434 of the rotatable head 1430. The rotatable head 1430 is configured to be rotatable in at least a first rotational direction 1436 with respect to a rotational axis 1499. The rotatable head 1430 can be rotated by a motor 1497, either directly, or with a gear train 1495. The peristaltic pump 1408 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 1408 can alternatively, or additionally be powered by a power cord 1493 configured to connect to a power supply. An extension tube 1438 having a distal end 1440 and a proximal end 1442, and having a lumen 1444 extending therethrough, is hydraulically coupled to the proximal end 1406' of the aspiration lumen 1404' via a connector 1424'. The extension tube 1438 can be supplied (e.g., sterile) with the aspiration catheter 1402', or can be packaged and supplied separately. A Touhy-Borst seal 1446' is coupleable and decoupleable to the connector 1424' (e.g., via luer connections 1750, 1752) and is configured to be loosened/opened to allow the insertion of a guidewire 1448 through the connector 1424' and the aspiration lumen 1404'. The aspiration lumen 1404' can thus be used to track the aspiration catheter 1402' over the guidewire 1448 through a subject's vasculature. The Touhy-Borst 1446' can be tightened to seal over the guidewire 1448, to maintain hemostasis. Other types of seals can be incorporated in place of the Touhy Borst 1446', including a spring-loaded, longitudinally compressible and actuatable seal. The distal end 1440 of the extension tube 1438 is slipped over a first barb fitting 1754 of a y-connector 1756. A second extension tube 1760 has a distal end 1761 that is slipped over a second barb fitting 1758 of the y-connector 1756. A third extension tube 1762 has a proximal end 1763 that is slipped over a third barb fitting 1764 of the y-connector 1756. The second extension tube 1760 and third extension tube 1762 are configured to operate under negative pressure without collapsing, and can comprise standard suction tubing. A distal end 1765 of the third extension tube 1762 is coupled to a female luer 1452' sideport of the connector 1424', either permanently by molding, or an adhesive bond or weld, or by an attachable and detachable connection, such as a luer 1766. The lengths of each of the second extension tube 1760 and third extension tube 1762 can be varied. In some embodiments, the third extension tube 1762 is relatively short, and the y-connector 1756 is configured to be located in a sterile area near the patient. In other embodiments, the third extension tube 1762 is configured to be relatively long, and the y-connector 1756 is configured to be located in a non-sterile area, away from the patient. The second extension tube 1760 is optional, as the third extension tube 1762 can have a much longer length and the pressure transducer 1416/aspiration monitoring system 1414 can be attached directly to the y-connector 1756 at the location of the barb fitting 1758. This connection can be direct, and so the barb fitting 1758 is also optional. With the longer third extension tube 1762, the y-connector 1756 and the aspiration monitoring system 1414 can both be close to the pump 1412, and can both reside in a non-sterile area.

[0223] In use, a compressible portion 1437 of the extension tube 1438 is placed within the pressure shoe 1428 of the peristaltic pump 1408 such that rotation of the rotatable head 1430 in the rotational direction 1436 causes fluid to be forced through the lumen 1444 of the extension tube 1438 from the distal end 1440 to the proximal end 1442, via compression of the compressible portion 1437 by the rollers 1432, one at a time. Optionally, an interface 1456 on the peristaltic pump 1408 is configured to allow a user to input information or commands to the peristaltic pump 1408 or other components of the system 1400'. Otherwise, hardware or firmware can be pre-programmed with specific run parameters (motor speed, rotation speed, etc.). In some embodiments, there are only two rollers 1432. In other embodiments, there are three rollers 1432. In still other embodiments, as shown, there are four rollers 1432. As described, the rollers 1432 can be replaced by bumps or protrusions. The compressible portion 1437 can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible section 1437 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 1438, or in other embodiments, can comprise the entirety of the extension tube 1438 between the distal end 1440 and the proximal end 1442. The proximal end 1442 of the extension tube 1438 can be coupled to a hub 1457 of a canister 1458 having an interior 1460, to allow fluid 1459 passing through the extension tube 1438 to pass into the interior 1460. An additional hub 1462 in the canister 1458 can be left open (as shown) to allow the unfilled interior 1460 to match atmospheric pressure. Alternatively, the canister 1458 can be replaced by a bag, such as an empty infusion bag, configured for collecting aspirate therein.

[0224] The aspiration catheter 1402' additionally has a high pressure injection lumen 1410' for injecting saline from a fluid source 1479, for example, via a high pressure pump 1412. A tubing set 1464 can include a pump cartridge 1466 having a piston or bellows or other movable element that the pump 1412 can manipulate using an internal motor 1491, thus pressurizing saline (or other fluid) from the fluid source 1479 with a significantly high pressure such that the saline is forced through the injection lumen 1410' of the aspiration catheter 1402'. The tubing set 1464 includes proximal end 1468 having a spike 1489, or other connecting element for hydraulically coupling the tubing set 1464 to the fluid source 1479. The tubing set 1464 further has a distal end 1470 (which can include a male luer) which is configured to hydraulically couple to the injection lumen 1410' via a female luer 1472'. In use, injected saline is forced through the injection lumen 1410' by the pump 1412 and exits an orifice 1474' at a distal end 1476' of the injection lumen 1410'. The injection lumen 1410' can extend within a separate tube 1478' (injection tube) that is substantially entirely within the shaft 1401'. In some embodiments, the tube 1478' is attached to the internal wall of the shaft 1401' only at a distal end portion 1403'. Thus, the free-floating nature of the remainder of the tube 1478' within the aspiration lumen 1404' increases the flexibility and trackability of the shaft 1401'. The high pressure saline is forced through the injection tube 1478' and out the orifice 1474', causing a jet (similar to jet 1487 of FIG. 36). The jet is aimed within the aspiration lumen 1404', just proximal the open distal end 1405' which can create a Venturi effect that forces blood or thrombus that is external and adjacent the open distal end 1405' into the aspiration lumen 1404'. The combination of the operation of the peristaltic pump 1408 and the jet created by the high pressure saline cause the maceration of throm-

bus, and the movement/flow of material (saline/blood/maccerated thrombus/small pieces of thrombus) through the aspiration lumen 1404' from the open distal end 1405' to the proximal end 1406', through the female luer 1452' of the connector 1424', and through the lumen 1444 of the extension tube 1438 from its distal end 1440 to its proximal end 1442, and finally into the interior 1460 of the canister 1458. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system 1400'. Blood vessels can include peripheral blood vessels, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

[0225] An aspiration monitoring system 1414 comprising a pressure transducer 1416 can be coupled, for example, proximal to the connector 1424' and/or proximal to the proximal end 1406' of the aspiration lumen 1404' of the aspiration catheter 1402', such that the pressure transducer 1416 is hydraulically coupled to the aspiration lumen 1404'. In the aspiration system 1400' of FIG. 38, the aspiration monitoring system 1414 is spaced a distance from the y-connector 1756 by a relatively long second extension tube 1760 (or alternatively by a relatively long third extension tube 1762, as in the aspiration system 2100 of FIG. 74) such that the aspiration monitoring system 1414 resides in a non-sterile area. Thus, the aspiration monitoring system 1414 can be set up, prepped, calibrated, and operated by a technologist, sales representative, nurse, or other medical personnel that has not "scrubbed" and thus does not need to maintain sterility. For example, the aspiration monitoring system 1414 can be located near the pump 1412, or on the same table as the pump 1412. The aspiration monitoring system 1414 can include any of the features described in relation to the other aspiration monitoring systems 48, 62, 78, 900, 1216, 1270 disclosed herein. Signals from the pressure transducer 1416 are carried on an electric cable 1480 to an input 1482 of the pump 1412. A controller 1484 within the pump 1412 is configured to control the operation of the pump 1412, including motor 1491, but the controller 1484 can also be configured to control the operation of the peristaltic pump 1408, via a cable 1486, or wirelessly. The controller 1484 can comprise a microcontroller. The controller 1484 can alternatively be located within the peristaltic pump 1408, or can be located at another location. Control using signals of measured pressure from the pressure transducer 1416 adds an additional safety element to the system 1400'. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Unallowably high pressures can also be quickly identified, protecting the motor 1491 of the pump 1412 from burnout or overheating danger. The integrity of the tube 1478' is also protected, e.g., avoiding unnaturally high pressures that could lead to burst.

[0226] The aspiration catheter 1402' is similar to the aspiration catheter 1402 of FIG. 36, except that the female luer 1452' is located distally on the connector 1424' from the female luer 1472'. Thus, aspirated blood/thrombus/saline enters the female luer 1452' without ever having to contact interior irregularities 1425' (in geometry, shape) within the connector 1424', that can otherwise cause flow resistance, or cause thrombus to catch (e.g., between the tube 1478' and the interior of the connector 1424').

[0227] A foot pedal 1451 has a base 1453 and a pedal 1455 that is coupled to the base 1453 and movable or activatable by application of the foot of a user. The pedal 1455 can be spring-loaded and depressible by application of a moment or a compressive force, or can instead comprise a membrane switch. The pedal 1455, when activated, can in some

embodiments toggle on and off, and in other embodiments can be activatable when a force, a pressure, or a moment is applied, and inactivated when the force, pressure, or moment is not applied. A first cable 1461 carries signals from the foot pedal 1451 to pump 1412 via a plug 1465 that is connected to an input jack 1467. In some embodiments, activation of the pedal 1455 by the foot of a user starts the operation of the pump 1412 and starts the operation of the peristaltic pump 1408 at the same time, as a signal through the first cable 1461 is received by the controller 1484, which commands the pump 1412 to start and, via the cable 1486, commands the peristaltic pump 1408 to start. In some embodiments, activation of the pedal 1455 by the foot of a user starts the operation of the peristaltic pump 1408, and then starts the operation of the pump 1412, with a slight delay after the peristaltic pump 1408 is started. The delay is useful to assure that some aspiration, or a significant amount of aspiration, is being applied to the aspiration lumen 1404' prior to the injection of pressurized fluid (e.g., saline) through the injection lumen 1410'. Thus, blood vessels or other vasculature in the vicinity of the open distal end 1405' are spared any injection of fluid from a high pressure jet, as it is instead aspirated through the aspiration lumen 1404', along with thrombus or blood. In some embodiments, the plug 1465 of the foot pedal 1451 can include a resistor 1759, and the pump 1412 can include an identification circuit 1757 configured to read the resistance value of the resistor 1759. For example, the resistor 1759 can complete a partial Wheatstone bridge carried on the identification circuit 1757, such that the pump 1412 can recognize the foot pedal 1451, and operate accordingly. Alternatively, the resistor 1759 can reside in the foot pedal 1451 itself, instead of the plug 1465. The cable 1461 can provide the electrical connection to the resistor 1759 in that particular case. Alternatively, the resistor 1759 can be replaced by an RFID chip that is configured to be powered and read by the identification circuit 1757.

[0228] In addition, in some embodiments, activation of the pedal 1455 by the foot of a user during the operation of the pump 1412 and the peristaltic pump 1408 stops the operation of the pump 1412 and the operation of the peristaltic pump 1408 at the same time. In other embodiments, a delay can be applied, for example, such that the pump 1412 is stopped, and then the peristaltic pump 1408 is stopped slightly afterwards. The length of the delays described can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. The operation (on/off) of the pump 1412 and/or peristaltic pump 1408 via the foot pedal 1451 allows hands-free activation, enabling a single user to manipulate the aspiration catheter 1402' and guidewire 1448 with both hands. The location of the foot pedal 1451 can be tactiley found with the foot of the user, while the user maintains visual contact with the patient and/or any monitors, or even other medical personnel. Alternatively, a second cable 1463 carries signals from the foot pedal 1451 directly to the peristaltic pump 1408 via a plug 1469 that is connected to an input jack 1471. Thus, the operation of the foot pedal 1451 can be configured to control the operation of the peristaltic pump 1408 in embodiments, for example, in which there is no cable 1486. However, in the embodiment of FIG. 38, which includes the cable 1486, the cable 1463 is not required.

[0229] In other embodiments, the foot pedal 1451 can be replaced by another type of switch, including, but not limited to a toggle on/off push button or hand switch, an audio-activated switch (voice activated, clap activated, click activated), an optical switch (beam/light sensor for hand or foot interruption), or any other kind of switch that can be

activated by medical personnel. The switch can be remote (e.g., in a control room) or can be located near the procedural area. The switch can also be a sterile switch or sterilizable for location on a sterile area.

[0230] In some cases, the activation and deactivation (turning on and off) of the aspiration flow applied by the peristaltic pump 1408 on the aspiration lumen 1404' can be done by leaving the peristaltic pump 1408 in a running condition, while the user opens and closes the stopcock 1454. In some embodiments, the controller 1484 controls the initiation of both the peristaltic pump 1408 and the pump 1412 at substantially the same time. In some embodiments, the controller 1484 controls the initiation the peristaltic pump 1408 and, following a particular delay, the initiation of the pump 1412. The delay can be within the ranges previously described.

[0231] The controller 1484 also monitors and controls several device safety functions, which include over pressure detection, air bubble detection, and vacuum or negative pressure charge. An additional pressure transducer 1415' carried on the connector 1424' monitors pressure (i.e. injection pressure), and senses the presence of air bubbles. Alternatively, or in conjunction, an optical device 1417' can be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed by the pump 1412 to produce that particular pressure. Consequently, if the electric current required by pump 1412 exceeds a preset limit, the controller 1484 will disable the pump 1412 by cutting power to it. Air bubble detection can also be monitored by monitoring the electrical current required to drive the pump 1412 at any particular moment. In order for a pump 1412 to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump 1412 or connecting system (including the aspiration lumen 1404' of the aspiration catheter 1402' and the tubing set 1464). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. A sufficient volume of liquid is needed proximally to flush any finite amount of air through. The controller 1484 monitors the pump 1412 current for any abrupt downward change that can indicate that air has entered the system. If the rate of drop is faster than a preset limit, the controller 1484 will disable the pump 1412 by cutting power to it until the problem is corrected.

[0232] In some embodiments, a fluid level sensor 1473 is carried on the side of the canister 1458 and is configured to sense when the canister 1458 has approached or reached its full level. The fluid level sensor 1473 is configured to output a signal through a cable 1475 that is attached to via an input 1477 (plug/jack) at the pump 1412. The signal from the fluid level sensor 1473 can be received by the controller 1484 which can be configured to immediately stop the pump 1412 and, via cable 1486, the peristaltic pump 1408 at the same time, or with a delay therebetween, as previously described. The fluid level sensor 1473 can comprise an optical sensor, and the canister 1458 can have a clear wall, to allow the optical sensor to measure the reflection variations when fluid is not adjacently present or when fluid is adjacently present. Alternatively, the fluid level sensor 1473 can comprise a piezoresistive pressure sensor that is within the volume 1460 of the canister 1458 at the desired height that represents a "full" canister 1458. Other types of fluid sensors are also contemplated, including floats, strain gauges, laser sensors, ultrasonic sensors, or capacitive sensors. In each of these embodiments, a signal is sent wirelessly or through cable

**1475** so that the peristaltic pump **1408** and/or pump **1412** can be shut down when a “full” level is reached.

[0233] In some embodiments, the peristaltic pump **1408** and the pump **1412** are combined into a single console. This allows for a smaller size that can be mounted on a standard IV pole. FIG. 74 illustrates an aspiration system **2100** that has all the features of the aspiration system, **1400'** of FIG. 38, but the peristaltic pump features **2108** and the injection pump features **2112** are both included on a single console **2102**. The third extension tube **1762** is elongated and the aspiration monitoring system **1414** is directly coupled or couplable to the y-connector **1756**. The aspiration monitoring system **1414** can reside in a non-sterile area. Thus, the aspiration monitoring system **1414** can be set up, prepped, calibrated, and operated by a technologist, sales representative, nurse, or other medical personnel that has not “scrubbed” and thus does not need to maintain sterility. For example, the aspiration monitoring system **1414** can be located on the same table as the console **2102**. The cable **1486** of the system **1400'** of FIG. 38 is not necessary, as similar connectivity is located inside the console **2100**. The cable **1463** of the system **1400'** of FIG. 38 is also not necessary, as the cable **1461** is capable of transferring all of the signals to and from the foot pedal **1451**. The luer **1766** can be attachable and detachable, or in other embodiments can be permanently bonded to the female luer **1452'** of the connector **1424'**.

[0234] FIG. 39 illustrates an alternative aspiration system **1400"** comprising the aspiration catheter **1402'** of FIG. 38. However, a centrifugal pump **1409** is substituted in place of the peristaltic pump **1408**. The proximal end **1442** of the extension tube **1438** coupled to an inlet **1413** which allows the aspirate to enter a chamber **1419**. An impeller **1421** is rotatably held within the chamber **1419** by a first bearing **1423** and a second bearing **1427**. A first seal **1429** and second seal **1431** allow the impeller **1421** to rotate (curved arrow) without the aspirate leaking. A motor **1433** is configured to rotate the impeller **1421**. The aspirate is forced out an outlet **1435** into an exit tube **1439** which is coupled to the hub **1457** of the canister **1458**. A user interface **1441** can be manipulated by a user to operate the centrifugal pump **1409**. In some embodiments, an Angiodynamics AngioVac centrifugal pump can be used as the centrifugal pump **1409**.

[0235] The aspiration catheters **1402**, **1402'** of FIGS. 36, 38, and 39 are illustrated as having pressurized fluid injection through injection lumens **1410**, **1410'**. However, other embodiments of the aspiration systems **1400**, **1400'** in which the aspiration catheters **1402**, **1402'** are replaced by a standard aspiration catheter, not having an injection lumen, such as the aspiration catheter **4** of FIG. 1.

[0236] As an alternative to collecting the aspirated material in a blood bag, blood bottle, or the canister **1458**, aspirated components (blood, thrombus, saline, slurry, etc.) can be placed into a reinfusion device, such as a Stryker ConstaVac (CBCII) Blood Conservation System, or a Haemonetics OrthoPAT Orthopedic Perioperative Autotransfusion System. The blood can be purified by the reinfusion device, for example, to remove red blood cells or portions of red blood cells that have undergone hemolysis. One such reinfusion device is the Haemonetics Cell Saver® Elite+ Autotransfusion System.

[0237] In some embodiments, the blood can be cooled prior to being injected. In some embodiments, the blood can be heated prior to being injected. In some embodiments, other drugs can be added to the blood prior to it being inserted. In some cases, the blood can be diluted with saline, to decrease its viscosity, or decrease its hematocrit. This can

allow for decrease hemolysis to occur. In some cases, blood collected in the canister **1458**, or blood coming from the extension tube **1438**, can even be used as donor blood, to infuse into a different patient.

[0238] In some embodiments, an additional or alternate sensor can be used to monitor flow conditions for the notification of the user, including, but not limited to: a Doppler sensor, an infrared sensor, or a laser flow detection device. In some embodiments, an externally-attached (non-contact) Doppler sensor can be employed. In some embodiments, an infrared sensor or a laser flow detection device can be employed around the aspiration tubing **1438**. The alternate sensor (e.g., flow sensor, etc.) can be located at a number of different locations along the aspiration path, including on or in the extension tube **1438**, distal to the impeller **1421** of the centrifugal pump **1409**, or on or in the exit tube **1439** proximal to the impeller **1421** of the centrifugal pump **1409**. Or in embodiments using a peristaltic pump **1408**, the alternate sensor can be located on or in the extension tube **1438**, distal or proximal to the rotatable head **1430** of the peristaltic pump **1408**.

[0239] An aspiration system **1600** utilizing an ultrasound sensor **1602** is shown in FIGS. 40-42. The aspiration system **1600** is similar to the aspiration system **1400'** of FIG. 38, with the addition of the ultrasound sensor **1602** and other related components. Alternative embodiments can utilize the teachings of other aspiration system embodiments disclosed herein. The ultrasound sensor can be configured for an analog output (e.g., with varying voltage output), for example, with a range of 0 Volts DC to 1 Volt DC, or 0 Volts DC to 5 Volts DC, or 0 Volts DC to 10 Volts DC. Turning to FIG. 41, the ultrasound sensor **1602** is inserted within a sideport **1606** of a y-connector **1604**. The y-connector **1604** has a distal connector **1608** attached to a proximal end **1603** of tubing **1610**. The tubing **1610** is slid over barbs **1605** which comprise the distal connector **1608**. A distal end **1607** of the tubing **1610** is coupled to the proximal end **1406'** of the aspiration lumen **1404'** of the aspiration catheter **1402'**, via a connector **1609** and the aspiration monitoring system **1414**, attached to the female luer **1452'** of the connector **1424'**. A proximal connector **1612** of the y-connector **1604** is connected to a friction fitting **1616** of an extension tube **1614**. The proximal connector **1612** also comprises barbs, The extension tube **1614** is connectable to the peristaltic pump **1608**, but can alternatively be coupled to the centrifugal pump **1409**, or one of the vacuum sources described herein. The ultrasound sensor **1602** is positioned so that its distal end **1618** is adjacent aspiration flow (straight arrow). A fitting **1620** at the proximal end of the ultrasound sensor **1602** is configured to secure the ultrasound sensor **1602** to the sideport **1606** in its desired position. This can be a friction fit, a screw attachment, a snap, and adhesive bond, a thermal bond, or other securing means. The output of the ultrasound sensor (e.g., voltage) is communicated through a cable **1622**. A strain relief **1601** coupled to the cable **1622** and the fitting **1620** serves to protect the first end **1611** of the cable **1622** from damage due to bending, tension, or compression.

[0240] In one embodiment, the ultrasound sensor **1602** has an analog channel that outputs a signal referenced to ground that varies between 0 to 5 Volts DC. For very small flow rates, the signal is often sinusoidal, but in the higher flow rates commonly occurring during the aspiration of clot/thrombus/blood the flow is substantial enough that it saturates the channel and appears as a variable digital pulse stream, roughly proportional to flow. The pulse frequency is relatively high on this channel. In other words, a pseudo-

digital on/off occurs when flow rates exceed a particular value. This particular value can be adjusted by connecting appropriate electronics. Along with the pseudo-digital properties of the channel, a dedicated digital I/O pin is utilized that feeds a high-priority interrupt handler. This allows the counting of rising signal transitions in this pulse stream very efficiently over a fixed interval of time. The pulse count above/below one or more pre-determined thresholds is ultimately what determines whether the overall system is in a free-flow or clot removal state and to what degree.

[0241] FIG. 42 illustrates a console 1624 having an input jack 1626 into which a plug 1628 at the second end 1613 of the cable 1622 attaches. The console 1624 includes an internal measurement device 1630 which is configured to count the number of times N during a predetermined time period P that a signal being output by the ultrasound sensor 1602 surpasses a predetermined threshold amplitude A. The measurement device 1630 is further configured to determine whether the number of times N is (a) greater than (or greater than or equal to) or (b) less than (or less than or equal to) a predetermined value V. For example, in one embodiment, a predetermined time period P is entered into the measurement device 1630 (e.g., via a user interface 1632) as 0.33 seconds. An algorithm within the measurement device 1630 counts the number threshold crossings that are output by the ultrasound sensor 1602 during this predetermined time period P. The measurement device 1630 then applies a particular logic scheme. In some embodiments, this logic scheme can simply be “flow” or “no flow.” For example, if there are between 0 counts and 150 counts within the time period P, then a “no flow” condition is identified and if there are 151 or greater counts within the time period P, then a “flow” condition is identified. The measurement device 1630 can comprise a microprocessor. A communication device 1634 carried on the console 1624 can be controlled by the measurement device 1630, or by a separate controller, to identify a first communication mode for the “no flow” condition and a second communication mode for the “flow” condition. In some embodiments, the first communication mode can comprise the non-existence of a signal (e.g., no light lit, no sound produced, no vibration or heat produced) from the communication device 1634, and the second communication mode can comprise a light lit, or a message shown (e.g., the word “flow”), or an audio message played (a voice stating “aspiration occurring”), or an audio warning (e.g., “beep”), or a mechanical warning (e.g., vibration). The amplitude of the communication (e.g., dB of sound, intensity of light, etc.) can be increased by pressing increase button 1615 or decreased by pressing decrease button 1617. The current level of the amplitude is displayed on display 1619. The display can comprise a series of LEDs 1621 that are configured to be lit up such that a higher amplitude corresponds to a larger number of the LEDs being lit.

[0242] In other embodiments, the first communication mode and the second communication mode can each include some perceptible signal (audible, visual, tactile), each one different from the other. In other embodiments, a more complex logic scheme can be used. For example, for a predetermined time period P of 0.33 seconds, if there are between 0 counts and 150 counts within the time period P, then a “no flow” condition is identified; if there are between 151 and 225 counts within the time period P, then a “low flow” condition is identified; if there are between 226 and 350 counts within the time period P, then a “medium flow” condition is identified; and, if there are 351 counts or greater, then a “high flow” condition is identified. The “no flow” condition can correspond to a first communication mode, the

“low flow” condition to a second communication mode, the “medium flow” condition to a third communication mode, and the “high flow” condition to a fourth communication mode. The first communication mode can be treated by the communication device 1634 remaining silent and/or non-visual/non-vibrational/non heating, etc. The second communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 2 Hz. The third communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 4 Hz. The fourth communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 10 Hz. In another embodiment, the second communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 0.5 Hz. The third communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 1 Hz. The fourth communication mode can be treated by the communication device beeping (via audio speaker) or flashing (via LED or other light) at a frequency of 2 Hz. Additionally, or alternatively, the intensity of the signal can increase from the second to the fourth communication modes. For example, by 10 dB from second to third and by 10 more dB from third to fourth. Or, by 5 dB, each time.

[0243] In an alternative embodiment, the ultrasound sensor 1602 can have an analog-to-digital module, and can output digital signals only, particular to 1 (flow at or above a particular threshold flow rate) or 0 (flow below a particular threshold flow rate).

[0244] The predetermined time period P, can be between about 0.01 seconds and about 1.00 seconds, or between about 0.10 seconds and about 0.50 seconds, or between about 0.20 seconds and about 0.40 seconds. The predetermined time period P can be adjustable by a user, for example, via the user interface 1632.

[0245] In certain aspiration procedures, when thrombus is not being sufficiently aspirated but aspiration continues, an unacceptably large volume of blood can be aspirated from the patient. This can cause dehydration, decreased blood pressure, or even exsanguination of the patient, all potentially serious events which can risk the success of the procedure and endanger the patient. The ability to be aware at all times whether the blood is being aspirated at an unacceptable rate is an important factor for achieving a high degree of safety and efficiency.

[0246] Systems for catheter aspiration are disclosed herein which are configured to communicate flow status and/or flow rate information to a user as determined by weighing the fluid, blood, thrombus, or other materials being aspirated from the patient over a period of time.

[0247] FIG. 43 illustrates an aspiration system 200 comprising an aspiration catheter 202 comprising an elongate shaft 201 including an aspiration lumen 204 having an open distal end 205 and a proximal end 206 configured to couple to a peristaltic pump 208. The peristaltic pump 208 can be a roller pump having a base 226, a pressure shoe 228 carried by the base 226, and a rotatable head 230, rotatably coupled to the base 226, and carrying two or more rollers 232a-d. The rollers 232a-d are arrayed around a perimeter 234 of the rotatable head 230. The rotatable head 230 is configured to be rotatable in at least a first rotational direction 236 (e.g., by a motor, directly, or with a gear train, as shown in FIG. 36). The peristaltic pump 208 can be battery powered, and

the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump **208** can alternatively, or additionally be powered by a power cord configured to connect to a power supply. An extension tube **238** having a distal end **240** and a proximal end **242**, and having a lumen **244** extending therethrough, is hydraulically coupled to the proximal end **206** of the aspiration lumen **204** of the aspiration catheter **202** via a connector **224**. The extension tube **238** can be supplied (e.g., sterile) with the aspiration catheter **202**, or can be packaged and supplied separately. A Touhy-Borst seal **246** carried on the connector **224** is configured to be loosened/opened to allow the insertion of a guidewire **248** through the connector **224** and the aspiration lumen **204**, which can be used to track the aspiration catheter **202** through a subject's vasculature. The Touhy-Borst **246** can be tightened to seal over the guidewire **248**, to maintain hemostasis. Other types of seals can be incorporated in place of the Touhy-Borst **246**, including a spring-loaded, longitudinally compressible and actuatable seal. The extension tube **238** includes a male luer **250** at its distal end **240**, for connecting to a female luer **252** of the connector **224**. Or, as shown, an aspiration monitoring system **214** can be attached therebetween. The male luer **250** can include a stopcock **254**, which is configured to be turned to select between an open position (shown) or a closed position. Alternatively, the extension tube **238** can be integral with the aspiration lumen **204**, or can be permanently attached to the connector **224**. In use, a compressible portion **237** of the extension tube **238** is placed within the pressure shoe **228** of the peristaltic pump **208** such that rotation of the rotatable head **230** (e.g., via input to an interface **256** by a user) in the rotational direction **236** causes fluid to be forced through the lumen **244** of the extension tube **238** from the distal end **240** to the proximal end **242**, via compression of the compressible portion **237** by the rollers **232**, one at a time. In some embodiments, there are only two rollers **232**. In other embodiments, there are three rollers **232**. In still other embodiments, as shown, there are four rollers **232**. As described, the rollers **232** can be replaced by bumps or protrusions. The compressible portion **237** can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible portion **237** can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube **238**, or in other embodiments, can comprise the entirety of the extension tube **238** between the distal end **240** and the proximal end **242**. The proximal end **242** of the extension tube **238** can be coupled to a hub **257** formed on a cap **213** of a canister **258**, the canister **258** having an interior **260**, to allow fluid **259** passing through the extension tube **238** to pass into the interior **260**. An additional hub **262** in the canister **258** can be provided, and can be left open (as shown) to allow the unfilled interior **260** to match atmospheric pressure.

**[0248]** In use, a distal section of the aspiration catheter **202** is inserted into the vasculature of a subject such that the open distal end **205** is adjacent or within a thrombus. Then, fluid, including thrombus, is aspirated into the aspiration lumen **204** by action of the peristaltic pump **208** and removed by use of the aspiration system **200**. Blood vessels treated can include peripheral blood vessels, pulmonary blood vessels, such as pulmonary arteries, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

**[0249]** The aspiration system **200** further comprises an aspiration monitoring system **1800** which is configured to provide information to a user concerning the status of aspiration. The aspiration monitoring system **1800** functions

by measuring the fluid **259** which has accumulated at the bottom of the interior **260** of the canister **258** at a plurality of points in time, thus estimating a (volumetric) flow rate of the fluid **259** issuing out the lumen **244** of the extension tube **238**. The aspiration monitoring system **1800** comprises a scale **1802** (or balance) having a base **1804**. A weighing platform **1806** is coupled to and movable with respect to the base **1804** (e.g., along a vertical axis V), such that the weight of the fluid **259** accumulated at the bottom of the canister **258** causes a signal **1808** indicative of the weight to be output. The scale can be configured to output a signal **1808** indicative of weight, or, in some embodiments, the particular elevation (above sea level) at which the scale **1802** resides can be input into the scale **1802** such that a value of mass can be output. A standard setting can assume that the procedure occurs at sea level, and can calculate mass accordingly. In some embodiments, the scale **1802** can even include an altimeter or other sensor to automatically determine elevation, such that mass can be output. Regardless, even when a weight is output, changes to the weight of the fluid **259** over time are proportional to changes to mass of the fluid **259** over time, at any particular elevation. Thus, the signal **1808** can be indicative of mass or indicative of weight, while remaining within the scope of allowing changes in the mass of the fluid **259** over time to be demonstrated. Thus, the system **200** can predict the loss of blood from the patient by its assessment of total cumulative weight/mass of blood captured in the canister **258**. Weight/mass of blood measured can be converted by the system **200** into volume of blood (ml) lost.

**[0250]** The signal **1808** is sent to a processor **1810**. See also, FIG. 44. The processor **1810**, which can comprise a microprocessor, includes a clock that allows the combination of time data with weight or mass values from the signal. In some embodiments, the scale **1802** can include a tare button or control, such that the tare weight of the canister **258** can be subtracted out from the amount being weighed by the scale **1802**. Thus, the scale **1802** is "zeroed" and only the weight or mass of the fluid **259** in the canister **258** is weighed at each time point. The sample rate at which values in the signal **1808** are obtained along with the time stamp can range between about 0.01 Hz and about 10 kHz, or between about 0.02 Hz and about 1 kHz, or between about 1 Hz and about 100 Hz. A processed signal **1812** is output to a graphic display **1814** for viewing by a user. In some embodiments, the graphic display **1814** can display an x-y graph **1816**, wherein the x-axis represents time and the y-axis represents weight or mass of the fluid **259** within the canister **258**. In other embodiments, the graphic display **1814** can display an x-y graph **1816**, wherein the x-axis represents time and the y-axis represents flow rate. The flow rate (FR) can be calculated from the formula:

$$FR = (W_c - W_p)/(T_c - T_p),$$

wherein

**[0251]**  $W_c$  is the current value for weight of the fluid **259**

**[0252]**  $W_p$  is the previous value of weight of the fluid **259**

**[0253]**  $T_c$  is the current time stamp value

**[0254]**  $T_p$  is the previous time stamp value

[0255] In other embodiments, the flow rate (FR) can be calculated from the formula:

$$FR = (W_c - W_{pn}) / (T_c - T_{pn}),$$

wherein

[0256]  $W_c$  is the current value for weight of the fluid 259

[0257]  $W_{pn}$  is the n<sup>th</sup> prior value of weight of the fluid 259

[0258]  $T_c$  is the current time stamp value

[0259]  $T_{pn}$  is the n<sup>th</sup> prior time stamp value

[0260] In other embodiments, the flow rate can be constructed as a moving average, such as a running average or rolling average. Several types of moving average can be used, including a simple moving average, a cumulative moving average, a weighted moving average, or an exponential moving average.

[0261] Instead of an x-y graph, a visual display comprising one or more LED lights can be used. For example, a higher flow rate can be indicated by a range of shades of green, while a lower flow rate can be indicated by a range of shades of red. Alternatively, the intensity of a light can be changed in response to changes in the flow rate, or changes in weight or mass. For example, the intensity of the light can be proportional to the measured/calculated flow rate. A loudspeaker can present the changes in weight/mass over time or changes in flow rate over time as a continuous or continual sound having a pitch that changes proportionally with changes in value. For example, a higher pitch with a larger flow rate. The sound intensity can alternatively be varied (higher flow rate=higher dB).

[0262] Changes in the flow rate can be indicative of a number of operation occurrences in the aspiration system 200. For example, a flow rate that suddenly decreases a significant amount can be indicative of thrombus becoming clogged within the aspiration lumen 204 or the lumen 244 of the extension tube 238. In some cases, a reduction in the flow rate of 90% or more can be indicative of clogging. When a clog occurs, the volume of fluid being aspirated and dispensed into the canister 258 can be severely limited. A loudspeaker 1818 is also configured to produce an audible alarm, when a threshold value of flow rate is crossed. A threshold flow rate can be input into a memory 1822 of the scale 1802 using a user interface 1820. When the flow rate decreases to a value below the threshold flow rate, the loudspeaker 1818 is made to sound an alarm. In some embodiments, a controller 215 in the peristaltic pump 208 can be coupled to the processor 1810 (wired or wireless) and can be configured to activate the alarm of the loudspeaker 1818. When the flow rate increases above the threshold flow rate, the loudspeaker 1818 can be deactivated such that the alarm is no longer sounded. Alternatively, the loudspeaker 1818 can be replaced by, or augmented with a visual alarm and/or a tactile alarm. The visual alarm can include one or more light, including one or more LEDs. The tactile alarm can include a vibration device, such as a piezoelectric, or a weight-offset rotational device.

[0263] Changes in the flow rate can also be indicative of other changes in status, such as a rupture in a wall of one of the tubular members or a disconnection of one of the connections. In one of these leak conditions, the flow rate can be significantly reduced, and thus identified by the flow rate changes measured by the aspiration monitoring system 1800. The system 200 can be configured to activate the alarm (e.g., via the loudspeaker 1818) when a free flow of

blood is detected. In other words, when the system is apparently aspirating only blood, and not aspirating thrombus. Thus, the measured flow rate crossing above a particular threshold stored in memory 1822 indicative of free flowing blood would cause the controller 215 to activate the alarm.

[0264] A secondary aspiration monitoring system 214 comprising a pressure transducer 216 can be coupled, for example, between the distal end 240 of the extension tube 238 and the connector 224 and/or proximal end 206 of the aspiration lumen 204 of the aspiration catheter 202. Signals from the pressure transducer 216 can be carried wirelessly or by a cable (not shown) to the controller 215. The controller 215 can comprise a microcontroller. The controller 215 can be located within the peristaltic pump 208, or can alternatively be located at another component or location. Control using measured pressure adds an additional safety element to the system 200. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Unallowably high pressures or low pressures can also be quickly identified, protecting the motor of the peristaltic pump 208 from burnout or overheating danger. Data from the pressure transducer 216 and the scale 1802 can be used together to optimize or create a more correct signal indicative of aspiration flow, or indicative of the presence of clot/thrombus, or the presence of a clog, or the presence of a burst or disconnection in the fluid circuit.

[0265] A foot pedal 251 is illustrated having a base 253 and a pedal 255 that is coupled to the base 253 and movable or activatable by application of the foot of a user. The pedal 255 can be spring-loaded and depressible by application of a moment or a compressive force, or can instead comprise a membrane switch. The pedal 255, when activated, can in some embodiments toggle on and off, and in other embodiments can be activatable when a force, a pressure, or a moment is applied, and inactivated when the force, pressure, or moment is not applied. A cable 263 carries signals from the foot pedal 251 to the peristaltic pump 208 via a plug 269 that is connected to an input jack 271. The pedal 255 can be activated by the foot of a user to start or stop the operation of the peristaltic pump 208.

[0266] In other embodiments, the foot pedal 251 can be replaced by another type of switch, including, but not limited to a toggle on/off push button or hand switch, an audio-activated switch (voice activated, clap activated, click activated), an optical switch (beam/light sensor for hand or foot interruption), or any other kind of switch that can be activated by medical personnel. The switch can be remote (e.g., in a control room) or can be located near the procedural area. The switch can also be a sterile switch or sterilizable for location on a sterile area.

[0267] In some cases, the activation and deactivation (turning on and off) of the aspiration flow applied by the peristaltic pump 208 on the aspiration lumen 204 can be done by leaving the peristaltic pump 208 in a running condition, while the user opens and closes the stopcock 254. Alternatively, a pinch valve (not shown) coupled to the extension tube 238 can be used for opening and closing the lumen 244, and thus starting and stopping aspiration. The pinch valve can be operated by a foot pedal (similar to the foot pedal 251), or can be operated by another control (e.g., on the interface 256 of the peristaltic pump 208).

[0268] After collecting the aspirated material in a blood bag, blood bottle, or the canister 258, aspirated components (blood, thrombus, saline, slurry, etc.) can be placed into a reinfusion device, such as a Stryker ConstaVac (CBCII)

Blood Conservation System, or a Haemonetics OrthoPAT Orthopedic Perioperative Autotransfusion System.

[0269] In some embodiments, the blood can be cooled prior to being injected. In some embodiments, the blood can be heated prior to being injected. In some embodiments, other drugs can be added to the blood prior to it being inserted. In some cases, the blood can be diluted with saline, to decrease its viscosity, or decrease its hematocrit. This can allow for decrease hemolysis to occur. In some cases, blood collected in the canister 258, or blood coming from the extension tube 238, can even be used as donor blood, to infuse into a different patient.

[0270] In some embodiments, an additional or alternate sensor can be used to monitor flow conditions for the notification of the user, including, but not limited to: a Doppler sensor, an infrared sensor, or a laser flow detection device. In some embodiments, an externally-attached (non-contact) Doppler sensor can be employed. In some embodiments, an infrared sensor or a laser flow detection device can be employed around the extension tubing 238. The alternate sensor (e.g., flow sensor, etc.) can be located at a number of different locations along the aspiration path, including on or in the extension tube 238, either proximal to or distal to the rotatable head 230 of the peristaltic pump 208.

[0271] FIG. 45 illustrates a forced aspiration system 400 comprising an aspiration catheter 402 comprising an elongate shaft 401 including an aspiration lumen 404 having an open distal end 405 and a proximal end 406 configured to couple to a peristaltic pump 408. The peristaltic pump 408 can be a roller pump having a base 426, a pressure shoe 428 carried by the base 426, and a rotatable head 430, rotatably coupled to the base 426, and carrying two or more rollers 432a-d. The rollers 432a-d are arrayed around a perimeter 434 of the rotatable head 430. The rotatable head 430 is configured to be rotatable in at least a first rotational direction 436 (e.g., by a motor, directly, or with a gear train, as shown in FIG. 36). The peristaltic pump 408 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 408 can alternatively, or additionally be powered by a power cord configured to connect to a power supply. An extension tube 438 having a distal end 440 and a proximal end 442, and having a lumen 444 extending therethrough, is hydraulically coupled to the proximal end 406 of the aspiration lumen 404 of the aspiration catheter 402 via a connector 424. The extension tube 438 can be supplied (e.g., sterile) with the aspiration catheter 202, or can be packaged and supplied separately. A Touhy-Borst seal 446 carried on the connector 424 is configured to be loosened/opened to allow the insertion of a guidewire 448 through the connector 424 and aspiration lumen 404, which can be used to track the aspiration catheter 402 through a subject's vasculature. The Touhy-Borst 446 can be tightened to seal over the guidewire 448, to maintain hemostasis. Other types of seals can be incorporated in place of the Touhy-Borst 246, including a spring-loaded, longitudinally compressible and actuatable seal. The extension tube 438 includes a male luer 450 at its distal end 440, for connecting to a female luer 452 of the connector 424. Or, as shown, an aspiration monitoring system 414 can be attached therebetween. The male luer 450 can include a stopcock 454, which is configured to be turned to select between an open position (shown) or a closed position. Alternatively, the extension tube 438 can be integral with the aspiration lumen 404, or can be permanently attached to the connector 424. In use, a compressible portion 437 of the extension tube 438 is placed within the pressure shoe 428 of the peristaltic pump 408 such that rotation of the

rotatable head 430 (e.g., via input to an interface 456 by a user) in the rotational direction 436 causes fluid to be forced through the lumen 444 of the extension tube 438 from the distal end 440 to the proximal end 442, via compression of the compressible portion 437 by the rollers 432, one at a time. In some embodiments, there are only two rollers 432. In other embodiments, there are three rollers 432. In still other embodiments, as shown, there are four rollers 432. As described, the rollers 432 can be replaced by bumps or protrusions. The compressible portion 437 can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible portion 437 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 438, or in other embodiments, can comprise the entirety of the extension tube 438 between the distal end 440 and the proximal end 442. The proximal end 442 of the extension tube 438 can be coupled to a hub 457 of a canister 458 having an interior 460, to allow fluid 459 passing through the extension tube 438 to pass into the interior 460. An additional hub 462 in the canister 458 can be left open (as shown) to allow the unfilled interior 460 to match atmospheric pressure. A filter 443 (optional) is placed in line between the extension tube 438 and canister 458 to catch thrombus that is aspirated from the patient. The filter 443 can have clear side walls so that the physician or other medical staff can visually assess the thrombus, such as the size of each piece, the number or pieces, the total amount of thrombus (e.g., volumetrically) or the condition of the thrombus or residual thrombus (organized/fibrous, or soft). The buildup of the thrombus within the filter 443, or lack thereof, can be utilized as a cue for moving the open distal end 405 of the aspiration catheter 402 to a different location, or temporarily or permanently stopping the procedure, or even increasing or decreasing the speed of the pump(s).

[0272] The aspiration catheter 402 additionally has a high pressure injection lumen 410 for injecting saline from a fluid source 499, for example, via a high pressure pump 412. A tubing set 464 can include a pump cartridge 466 having a piston or bellows or other movable element that the pump 412 can manipulate using an internal motor (not shown), this applying a high pressure to saline from the fluid source 499 such that the saline is forced through the injection lumen 410 of the aspiration catheter 402. The tubing set 464 includes proximal end 468 having a spike 497 or other element for hydraulically coupling it to the fluid source 499. The tubing set 464 further has a distal end 470 (which can include a male luer) which is configured to hydraulically couple to the injection lumen 410 via a female luer 472. Injected saline is forced through the injection lumen 410 by the pump 412 and exits an orifice 474 at a distal end 476 of the injection lumen 410. The injection lumen 410 can be within a tube 478 that is substantially or entirely within the shaft 401. In some embodiments, the tube 478 is attached to the internal wall of the shaft 401 only at a distal end portion 403. Thus, the free-floating nature of the remainder of the tube 478 within the aspiration lumen 404 increases the flexibility and trackability of the shaft 401. The high pressure saline is forced through the orifice 474, causing a jet. The jet is aimed within the aspiration lumen 404, just proximal the open distal end 405 which can create a Venturi effect that forces blood or thrombus external and adjacent the open distal end 405 into the aspiration lumen 404. The combination of the operation of the peristaltic pump 408 and the jet caused by the high pressure saline cause the maceration of thrombus, and the movement/flow of material (saline/blood/macerated thrombus/small pieces of thrombus) through the aspiration lumen

**404** from the open distal end **405** to the proximal end **406**, through the connector **424**, and through the lumen **444** of the extension tube **438** from its distal end **440** to its proximal end **442**, and finally into the interior **460** of the canister **458**. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system **400**. Blood vessels treated can include peripheral blood vessels, pulmonary blood vessels, such as pulmonary arteries, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

[0273] The forced aspiration system **400** further comprises an aspiration monitoring system **1800** which is configured to provide information to a user concerning the status of aspiration. The aspiration monitoring system **1800** functions by measuring the fluid **459** which has accumulated at the bottom of the interior **460** of the canister **458** at a plurality of points in time, thus estimating a flow rate of the fluid **459** issuing out the lumen **444** of the extension tube **438**. The aspiration monitoring system **1800** comprises a scale **1802** (or balance) having a base **1804**. A weighing platform **1806** is coupled to and movable with respect to the base **1804** (e.g., along a vertical axis V), such that the weight of the fluid **459** accumulated at the bottom of the canister **458** causes a signal **1808** indicative of the weight to be output. The scale can be configured to output a signal **1808** indicative of weight, or, in some embodiments, the particular elevation (above sea level) at which the scale **1802** resides can be input into the scale **1802** such that a value of mass can be output. In some embodiment, the scale **1802** can even include an altimeter or other sensor to automatically determine elevation, such that mass can be output. Regardless, even when a weight is output, changes to the weight of the fluid **459** over time are proportional to changes to mass of the fluid **459** over time, at any particular elevation. Thus, the signal **1808** can be indicative of mass or indicative of weight, while remaining within the scope of allowing changes in the mass of the fluid **459** over time to be demonstrated. Thus, the system **400** can predict the loss of blood from the patient by its assessment of total cumulative weight/mass of blood captured in the canister **458**. Weight/mass of blood measured can be converted by the system **400** into volume of blood (ml) lost.

[0274] The signal **1808** is sent to a processor **1810**. See also, FIG. 44. The processor **1810**, which can comprise a microprocessor, includes a clock that allows the combination of time data with weight or mass values from the signal. In some embodiments, the scale **1802** can include a tare button or control, such that the tare weight of the canister **458** can be subtracted out from the amount being weighed by the scale **1802**. Thus, the scale **1802** is "zeroed" and only the weight or mass of the fluid **459** in the canister **458** is weighed at each time point. The sample rate at which values in the signal **1808** are obtained along with the time stamp can range between about 0.01 Hz and about 10 kHz, or between about 0.02 Hz and about 1 kHz, or between about 1 Hz and about 100 Hz. A processed signal **1812** is output to a graphic display **1814** for viewing by a user. In some embodiments, the graphic display **1814** can display an x-y graph **1816**, wherein the x-axis represents time and the y-axis represents weight or mass of the fluid **459** within the canister **458**. In other embodiments, the graphic display **1814** can display an x-y graph **1816**, wherein the x-axis represents time and the y-axis represents flow rate. The flow rate (FR) can be calculated from the formula:

$$FR = (W_c - W_p)/(T_c - T_p),$$

wherein

[0275]  $W_c$  is the current value for weight of the fluid

**459**

[0276]  $W_p$  is the previous value of weight of the fluid

**459**

[0277]  $T_c$  is the current time stamp value

[0278]  $T_p$  is the previous time stamp value

[0279] In other embodiments, the flow rate (FR) can be calculated from the formula:

$$FR = (W_c - W_{pn})/(T_c - T_{pn}),$$

wherein

[0280]  $W_c$  is the current value for weight of the fluid

**459**

[0281]  $W_{pn}$  is the  $n^{th}$  prior value of weight of the fluid

**459**

[0282]  $T_c$  is the current time stamp value

[0283]  $T_{pn}$  is the  $n^{th}$  prior time stamp value

[0284] In other embodiments, the flow rate can be constructed as a moving average, such as a running average or rolling average. Several types of moving average can be used, including a simple moving average, a cumulative moving average, a weighted moving average, or an exponential moving average.

[0285] Instead of an x-y graph, a visual display comprising one or more LED lights can be used. For example, a higher flow rate can be indicated by a range of shades of green, while a lower flow rate can be indicated by a range of shades of red. Alternatively, the intensity of a light can be changed in response to changes in the flow rate or changes in weight or mass. For example, the intensity of the light can be proportional to the measured/calculated flow rate. A loudspeaker can present the changes in weight/mass over time or changes in flow rate over time as a continuous or continual sound having a pitch that changes proportionally with changes in value. For example, a higher pitch with a larger flow rate. The sound intensity can alternatively be varied (higher flow rate=higher dB).

[0286] Changes in the flow rate can be indicative of a number of operation occurrences in the forced aspiration system **400**. For example, a flow rate that suddenly decreases a significant amount can be indicative of thrombus becoming clogged within the aspiration lumen **404** or the lumen **444** of the extension tube **438**. In some cases, a reduction in the flow rate of 90% or more can be indicative of clogging. When a clog occurs, the volume of fluid being aspirated and dispensed into the canister **458** can be severely limited. A loudspeaker **1818** is also configured to produce an audible alarm, when a threshold value of flow rate is crossed. A threshold flow rate can be input into memory **1822** of the scale **1802** using a user interface **1820**. When the flow rate decreases to a value below the threshold flow rate, the loudspeaker **1818** is made to sound an alarm. In some embodiments, the controller **484** on the pump **412**, or a different controller in one of the other components can be coupled to the processor **1810** (wired or wireless) and can be configured to activate the alarm of the loudspeaker **1818**. When the flow rate increases above the threshold flow rate, the loudspeaker **1818** can be deactivated such that the alarm is no longer sounded. Alternatively, the loudspeaker **1818**

can be replaced by, or augmented with a visual alarm and/or a tactile alarm. The visual alarm can include one or more light, including one or more LEDs. The tactile alarm can include a vibration device, such as a piezoelectric, or a weight-offset rotational device.

[0287] Changes in the flow rate can also be indicative of other changes in status, such as a rupture in a wall of one of the tubular members or a disconnection of one of the connections. In one of these leak conditions, the flow rate can be significantly reduced, and thus identified by the flow rate changes measured by the aspiration monitoring system 1800. The system 400 can be configured to activate the alarm (e.g., via the loudspeaker 1818) when a free flow of blood is detected. In other words, when the system is apparently aspirating only blood, and not aspirating thrombus. Thus, the measured flow rate crossing above a particular threshold stored in memory 1822 indicative of free flowing blood would cause the controller 484 to activate the alarm.

[0288] A secondary aspiration monitoring system 414 comprising a pressure transducer 416 can be coupled, for example, between the distal end 440 of the extension tube 438 and the connector 424 and/or proximal end 406 of the aspiration lumen 404 of the aspiration catheter 402. Signals from the pressure transducer 416 are carried on an electric cable 480 to an input 482 of the pump 412. The controller 484 within the pump 412 is configured to control the operation of the pump 412, but also can be configured to control the operation of the peristaltic pump 408, via a cable 486, or wirelessly. The controller 484 can comprise a microcontroller. The controller 484 can alternatively be located within the peristaltic pump 408, or can be located at another component or location. Control using measured pressure adds an additional safety element to the system 400. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Unallowably high pressures can also be quickly identified, protecting the motor of the pump 412 from burnout or overheating danger. The integrity of the tube 478 is also protected, e.g., avoiding unnaturally high pressures that could lead to a burst of the tube 478. Data from the pressure transducer 416 and the scale 1802 can be used together to optimize or create a more correct signal indicative of aspiration flow, or indicative of the presence of clot/thrombus, or the presence of a clog, or the presence of a burst or disconnection in the fluid circuit.

[0289] The female luer 452 is located distally on the connector 424 from the female luer 472. Thus, aspirated blood/thrombus/saline enters the female luer 452 without ever having to contact interior irregularities 425 (in geometry, shape) within the connector 424, that can otherwise cause flow resistance, or cause thrombus to catch (e.g., between the tube 478 and the interior of the connector 424).

[0290] A foot pedal 451 is illustrated having a base 453 and a pedal 455 that is coupled to the base 453 and movable or activatable by application of the foot of a user. The pedal 455 can be spring-loaded and depressible by application of a moment or a compressive force, or can instead comprise a membrane switch. The pedal 455, when activated, can in some embodiments toggle on and off, and in other embodiments can be activatable when a force, a pressure, or a moment is applied, and inactivated when the force, pressure, or moment is not applied. A first cable 461 carries signals from the foot pedal 451 to the pump 412 via a plug 465 that is connected to an input jack 467. A second cable 463 carries signals from the foot pedal 451 to the peristaltic pump 408 via a plug 469 that is connected to an input jack 471. In some embodiments, activation of the pedal 455 by the foot of a

user starts the operation of the pump 412 and starts the operation of the peristaltic pump 408 at the same time. In some embodiments, activation of the pedal 455 by the foot of a user starts the operation of the peristaltic pump 408, and then starts the operation of the pump 412, with a slight delay after the peristaltic pump 408 is started. The controller 484 is programmed or programable to impart the delay, or the lack of delay. The delay is useful to assure that some aspiration, or a significant amount of aspiration, is being applied to the aspiration lumen 404 prior to the injection of pressurized fluid (e.g., saline) through the injection lumen 410. All can be controlled by the controller 484 of the pump 412, in response to a signal through the cable 463 from the foot pedal 451. Thus, blood vessels or other vasculature in the vicinity of the open distal end 405 are spared any injection of fluid from a high pressure jet, as it is instead aspirated through the aspiration lumen 404.

[0291] In addition, in some embodiments, activation of the pedal 455 by the foot of a user during the operation of the pump 412 and the peristaltic pump 408 stops the operation of the pump 412 and the operation of the peristaltic pump 408 at the same time. In other embodiments, a delay can be applied (e.g., by the controller 484), such that the pump 412 is stopped, and then the peristaltic pump 408 is stopped slightly afterwards. The length of the delays described can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. The operation (on/off) of the pump 412 and/or peristaltic pump 408 via the foot pedal 451 allows hands-free activation, enabling a single user to manipulate the aspiration catheter 402 and guidewire 448 with both hands.

[0292] In other embodiments, the foot pedal 451 can be replaced by another type of switch, including, but not limited to a toggle on/off push button or hand switch, an audio-activated switch (voice activated, clap activated, click activated), an optical switch (beam/light sensor for hand or foot interruption), or any other kind of switch that can be activated by medical personnel. The switch can be remote (e.g., in a control room) or can be located near the procedural area. The switch can also be a sterile switch or sterilizable for location on a sterile area.

[0293] In some cases, the activation and deactivation (turning on and off) of the aspiration flow applied by the peristaltic pump 408 on the aspiration lumen 404 can be done by leaving the peristaltic pump 408 in a running condition, while the user opens and closes the stopcock 454. Alternatively, a pinch valve (not shown) coupled to the extension tube 438 can be used for opening and closing the lumen 444, and thus starting and stopping aspiration. The pinch valve can be operated by a foot pedal (similar to the foot pedal 451), or can be operated by another control (e.g., on the interface 456 of the peristaltic pump 408 or even an interface on the pump 412).

[0294] The controller 484 also monitors and controls several device safety functions, which include over pressure detection, air bubble detection, and vacuum or negative pressure charge. An additional pressure transducer 415 monitors pressure (i.e. injection pressure), and senses the presence of air bubbles. Alternatively, or in conjunction, an optical device 417 can be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed to produce that pressure. Consequently, if the electric current required by pump 412 exceeds a preset limit, the controller 484 will disable the pump 412 by cutting power to it. Air bubble detection can also be monitored by monitoring the electrical current required to drive the pump 412 at any particular moment. In

order for a pump 412 to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump 412 or connecting system (including the aspiration lumen 404 of the aspiration catheter 402 and the tubing set 464). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. A sufficient volume of liquid is needed proximally to flush any finite amount of air through. The controller 484 monitors the pump 412 current for any abrupt downward change that can indicate that air has entered the system. If the rate of drop is faster than a preset limit, the controller 484 will disable the pump 412 by cutting power to it until the problem is corrected.

[0295] After collecting the aspirated material in a blood bag, blood bottle, or the canister 458, aspirated components (blood, thrombus, saline, slurry, etc.) can be placed into a reinfusion device, such as a Stryker ConstaVac (CBCII) Blood Conservation System, or a Haemonetics OrthoPAT Orthopedic Perioperative Autotransfusion System.

[0296] In some embodiments, the blood can be cooled prior to being injected. In some embodiments, the blood can be heated prior to being injected. In some embodiments, other drugs can be added to the blood prior to it being inserted. In some cases, the blood can be diluted with saline, to decrease its viscosity, or decrease its hematocrit. This can allow for decrease hemolysis to occur. In some cases, blood collected in the canister 458, or blood coming from the extension tube 438, can even be used as donor blood, to infuse into a different patient.

[0297] In some embodiments, an additional or alternate sensor can be used to monitor flow conditions for the notification of the user, including, but not limited to: a Doppler sensor, an infrared sensor, or a laser flow detection device. In some embodiments, an externally-attached (non-contact) Doppler sensor can be employed. In some embodiments, an infrared sensor or a laser flow detection device can be employed around the extension tubing 438. The alternate sensor (e.g., flow sensor, etc.) can be located at a number of different locations along the aspiration path, including on or in the extension tube 438, either proximal to or distal to the rotatable head 430 of the peristaltic pump 408.

[0298] FIG. 46 illustrates an alternative aspiration monitoring system 1900 that shares features with the aspiration monitoring system 1800 of FIG. 44, but is configured to weigh the fluid 259, 459 contained in the canister 258, 458 by suspending the canister 258, 458 from hooks 1902, 1904 that extend from a frame 1906 that is supported on the weighing platform 1806. The frame 1906 comprises two vertical legs 1910, 1912 and a crossbar 1908 coupled to each of the vertical legs 1910, 1912. The crossbar 1908 is configured to support the hooks 1902, 1904 and the canister 258, 458 (when hung). The canister 258, 458 can include hooks, indentations, or loops that are configured to engagingly interface with one or both of the hooks 1902, 1904.

[0299] While the foregoing is directed to embodiments of the present disclosure, other and further embodiments can be devised without departing from the basic scope thereof. Alternatively, instead of using the extension tube 238, 438 that is configured to be used with a peristaltic pump 208, 408, an extension tube 238, 438 can comprise a luer connector (or other sealing connector) at its proximal end, and can be configured to be attached to an evacuable syringe (e.g., 20 ml or 30 ml). The syringe can be hung from the hooks 1902, 1904 (or the equivalent) and the weight of the syringe and extension tube 238, 438 can be tared from the scale 1802. Thus, as the syringe fills, the increase of weight/mass of the aspirate collecting in the syringe is measured over

time, in the same manner that the contents of the canister 258, 458 is weighed. The evacuable syringe can even be replaced by a bell jar connected to a vacuum pump, again, with the bell jar and any connecting tubing tared from the measured weight/mass. FIG. 47 illustrates an aspiration system 1928 similar to the aspiration system 200 of FIG. 43, except that the peristaltic pump 208 and canister 258 are replaced by a vacuum pump 1930 and a vacuum chamber 1934 or bell jar having a base 1936 and a lid 1938 sealably placed thereon. The vacuum pump 1930 can be operated by controls 1999 carried on its outer surface 1997, or can be controllable (on/off) by the foot pedal 251. A vacuum tubing 1932 connects the vacuum pump 1930 to an interior 1940 of the vacuum chamber 1934. A control valve 1948 is adjustable for controlling the aperture between the vacuum tubing 1932 and the interior 1940 of the vacuum chamber 1934. The interior 1940 communicates with the lumen 244 of the extension tube 238 via the proximal end 242, which is coupled to a port 1942 of the vacuum chamber 1934. An adjustable valve 1946 controls an aperture between the interior 1940 of the vacuum chamber 1934 and the lumen 244 of the extension tube 238. The vacuum pump 1930 is supported separately on a table, cart, or other support. The weight of the vacuum tubing 1932 and extension tube 238 can be tared from the readout of the scale 1802, so that only the weight of fluid/clot, etc. pulled into the interior 1940 of the vacuum chamber 1934 is measured over time.

[0300] Thrombosis (thrombus, clot) within vasculature, including blood vessels such as arteries or veins, is a significant risk factor that can be debilitating or even cause death. Aspiration systems including aspiration catheter include aspiration-only devices as well as forced aspiration devices, which are configured to inject pressurized fluid, such as heparinized saline, into the distal portion of an aspiration lumen, to create a larger aspiration pressure gradient, and thus more significant thrombus maceration and removal. Though many of these aspiration systems are used in peripheral or coronary arteries, thromboembolic stroke involving arteries of the neck and head is also of concern. Many of the arteries of the neck and head, including cerebral arteries, the basilar artery, and other communicating arteries in proximity, are located quite a distance from traditional insertion/puncture locations, such as the femoral artery or radial artery. The pathway to these arteries can also be quite tortuous, and the vessels are often of a small caliber, such that long, small diameter catheters with a great deal of flexibility at their distal ends are utilized. Many of these design criteria confound other physical requirements of an aspiration catheter, such as a large diameter aspiration lumen for increased aspiration flow, or the multiple lumens of a force aspiration catheter, which must now fit into a small overall catheter shaft diameter.

[0301] Clogging of aspiration catheters, for example by large pieces of thrombus, is a common concern for users. Techniques to avoid clogging/choking of material within the catheter often involve rapidly, aggressively advancing the aspiration catheter or gently plucking at edges of a thrombus to insure only small pieces or portions are introduced at a time, pieces which are small enough to not clog or occlude the aspiration lumen. When a device becomes clogged during use, the potential for inadvertent dislodgment of thrombus downstream increases; this is referred to as distal embolism. As aspiration procedures of this type are often used in highly technical emergent settings, early clog detection of the aspiration catheter for the user during aspiration can contribute to the success of the procedure and clinical

outcome. Some sources have reported that up to 50% of aspiration catheters used get clogged during use.

**[0302]** The user may have difficulty determining whether there is a vacuum or a negative pressure gradient in the system or not. For example, the user may have difficulty determining whether the vacuum or negative pressure has been applied or not (e.g., the vacuum source or negative pressure supplying pump has been turned on or off). Additionally, the user may have difficulty determining whether there has been a loss of vacuum or negative pressure in the system, for example because of the syringe (or other vacuum source or negative pressure supplying pump) being full of fluid or because of a leak in the system. Blood is relatively opaque and can coat the wall of the syringe, thus making it difficult to determine when the syringe becomes full. This makes it difficult to determine whether sufficient vacuum or negative pressure is being applied to the aspiration catheter. The vacuum or negative pressure level can change to an unacceptable level even before the syringe becomes full. Extension tubing or other tubing can also cause a loss in vacuum or negative pressure gradient in the system. Certain tubing kinks can be difficult for a user to see or identify. It is also difficult to determine whether there is an air leak in the system, which can be another cause for a loss of vacuum or negative pressure even before the syringe becomes full of the aspirated fluid.

**[0303]** FIG. 48 illustrates an aspiration system 600 comprising an aspiration catheter 602 comprising an elongate shaft 601 including an aspiration lumen 604 having an open distal end 605 and a proximal end 606 configured to couple to a peristaltic pump 608. The peristaltic pump 608 can be a roller pump having a base 626, a pressure shoe 628 carried by the base 626, and a rotatable head 630, rotatably coupled to the base 626, and carrying two or more rollers 632a-d. The rollers 632a-d are arrayed around a perimeter 634 of the rotatable head 630. The rotatable head 630 is configured to be rotatable in at least a first rotational direction 636 (e.g., by a motor, directly, or with a gear train, not shown). The peristaltic pump 608 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 608 can alternatively, or additionally be powered by a power cord (not shown) configured to connect to a power supply. An extension tube 638 having a distal end 640 and a proximal end 642, and having a lumen 644 extending therethrough, is hydraulically coupled to the proximal end 606 of the aspiration lumen 604 via a connector 624. A Touhy-Borst seal 646 allows the insertion of a guidewire 648 through the connector 624 and aspiration lumen 604, as described herein, and the guidewire 648 can be used to track the aspiration catheter 602 through a subject's vasculature. The Touhy-Borst 646 can be tightened to seal over the guidewire 648, to maintain hemostasis. The extension tube 638 can include a male luer 650 at its distal end 640, for connecting to a female luer 652 of the connector 624. The male luer 650 can include a stopcock 654, which is configured to be turned between an open position (shown) or a closed position. Alternatively, the extension tube 638 can be integral with the aspiration lumen 604, or can be permanently attached to the connector 624. In use, a compressible portion 637 of the extension tube 638 is placed within the pressure shoe 628 of the peristaltic pump 608 such that rotation of the rotatable head 630 (e.g., via input to an interface 656 by a user) in the rotational direction 636 causes fluid to be forced through the lumen 644 of the extension tube 638 from the distal end 640 to the proximal end 642, via compression of the compressible portion 637 by the rollers 632, one at a time. In some embodiments, there

are only two rollers 632. In other embodiments, there are three rollers 632. In still other embodiments, as shown, there are four rollers 632. As described, the rollers 632 can be replaced by bumps or protrusions. The compressible portion 637 or any of the compressible portions described herein can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, thermoplastic elastomer (TPE), such as Bioprene®, a registered trademark of Watson-Marlow or Wilmington, MA, USA, or other compressible tubing. The compressible section 637 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 638, or in other embodiments, can comprise the entirety of the extension tube 638 between the distal end 640 and the proximal end 642. The proximal end 642 of the extension tube 638 can be coupled to a canister 658 having an interior 660, to allow fluid 659 passing through the extension tube 638 to pass into the interior 660. The proximal end 642 of the extension tube 638 is coupled to the canister 658 by a tubing clamp 657 which holds the extension tube 638 longitudinally without compromising the patency of the lumen 644. To minimize fluid resistance at the proximal end 642 of the extension tube, besides an endhole 621, there is also a plurality of sideholes 623, similar to sump tubing. In other embodiments, the endhole 621 can be blocked off, with the outflow emanating only from the plurality of sideholes 623. The sideholes 623 assure that the minimum area of flow resistance in the extension tube 638 is not at the proximal end 642. The sideholes 623 help prevent against jetting into the canister 658. Jetting of the blood would be a negative factor, adding shear stress to the blood, and causing hemolysis or platelet activation, and thus damaging or otherwise altering blood that might have been desired for reinfusion into the patient. An additional hub 662 in the canister 658 can be left open (as shown) to allow the unfilled interior 660 to match atmospheric pressure.

**[0304]** Because the aspiration catheter 602 is configured to be inserted into arteries that can feed to critical organs (heart, brain, etc.), strict control of flows through the catheter allows for a higher level of security. A recognition system is provided to assure that the aspiration catheter 602 is only used with the peristaltic pump 608 and the injection pump 612, and not with alternative devices that do not have the same levels of control regarding aspiration and injection. An identification circuit 619 within the peristaltic pump 608 is coupled to the controller 684 (e.g., via cable 686) and also electrically connects to a first port 611 and a second port 613. The extension tube 638 can be provided with a first tether 690 having a first identification module 607 configured to plug into or otherwise be secured in close proximity to the first port 611. Additionally, or alternatively, the aspiration catheter 602 can be provided with a second tether 688 having a second identification module 609 configured to plug into or otherwise be secured in close proximity to the second port 613. The controller 684 is configured to only allow the operation of the injection pump 612 and/or the peristaltic pump 608 to occur if one of both of the identification modules 607, 609 are identified by the identification circuit 619 as being correct components (e.g., correct models, correct sizes, correct clinical applications, etc.). Thus, the pumps 612, 608 are enabled or un-enabled by the controller 684, depending upon the information provided by the identification modules 607, 609. In some embodiments one or both of the identification modules 607, 609 make comprise an RFID (radiofrequency identification) chip, and the identification circuit 619 configured to power the RFID chips to receive and read data. In some embodiments, the identification circuit 619 can additionally be configured to

write to the RFID chips. In other embodiments one or both of the identification modules 607, 609 make comprise a resistor, and the identification circuit 619 configured to read the resistance value of the resistor. For example, the resistor can complete a partial Wheatstone bridge carried on the identification circuit 619.

[0305] The aspiration catheter 602 additionally has a high pressure injection lumen 610 for injecting saline from a fluid source 679, for example, via a high pressure pump 612. A tubing set 664 can include a pump cartridge 666 having a piston or bellows or other movable element that the pump 612 can manipulate using an internal motor 691, thus pressurizing saline or other fluid from the fluid source 679 with a significantly high pressure such that the saline is forced through the injection lumen 610 of the aspiration catheter 602. The tubing set 664 includes proximal end 668 having a spike 689 or other element for hydraulically coupling it to the fluid source 679. The tubing set 1464 further has a distal end 670 (which can include a male luer) which is configured to hydraulically couple to the injection lumen 610 via a female luer 672. Injected saline is forced through the injection lumen 610 by the pump 612 and exits an orifice 674 in a hollow end piece 675 coupled to a distal end 676 of an injection tube 678, containing the injection lumen 610. The tube 678 can be substantially or entirely within the shaft 601. In some embodiments, the tube 678 is attached to the internal wall of the shaft 601 only at a distal end portion 603. Thus, the free-floating nature of the remainder of the tube 678 within the aspiration lumen 604 increases the flexibility and trackability of the shaft 601. The high pressure saline is forced through the orifice 674, causing a jet, or one or more jets. The jet is aimed within the aspiration lumen 604, just proximal the open distal end 605 which can create a Venturi effect that forces blood or thrombus that is external and adjacent the open distal end 605 into the aspiration lumen 640. The combination of the operation of the peristaltic pump 608 and the jet created by the high pressure saline cause the maceration of thrombus, and the movement/flow of material (saline/blood/macerated thrombus/small pieces of thrombus) through the aspiration lumen 604 from the open distal end 605 to the proximal end 606, through the connector 624, and through the lumen 644 of the extension tube 638 from its distal end 640 to its proximal end 642, and finally into the interior 660 of the canister 658. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system 600. Blood vessels can include peripheral blood vessels, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries, cerebral arteries, and basilar and communicating arteries. An aspiration monitoring system 614 comprising a pressure transducer 616 can be coupled, for example, between the distal end 640 of the extension tube 638 and the connector 624 and/or proximal end 606 of the aspiration lumen 604 of the aspiration catheter 602. The aspiration monitoring system 614 or any other described herein can include any of the features described in relation to aspiration monitoring systems described in U.S. Pat. App. Pub. No. 2017/0056032 to Look et al., filed Aug. 23, 2016 and published Mar. 2, 2017, which is hereby incorporated by reference in its entirety for all purposes. Signals from the pressure transducer 616 are carried on an electric cable 680 to an input 682 of the pump 612. A controller 684 within the pump 612 is configured to control the operation of the pump 612, including motor 691, but the controller 684 can also be configured to control the operation of the peristaltic pump 608, via a cable 686, or wirelessly. The controller 684 can comprise a microcon-

troller. The controller 684 can alternatively be located within the peristaltic pump 608, or can be located at another location. Control using signals of measured pressure from the pressure transducer 616 adds an additional safety element to the system 600. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Unallowably high pressures can also be quickly identified, protecting the motor 691 of the pump 612 from burnout or overheating danger. The integrity of the tube 678 is also protected, e.g., avoiding unnaturally high pressures that could lead to burst.

[0306] The female luer 652 of the aspiration catheter 602 is located distally on the connector 624 from the female luer 672. Thus, aspirated blood/thrombus/saline enters the female luer 652 without ever having to contact interior irregularities 625 (in geometry, shape) within the connector 624, that can otherwise cause flow resistance, or cause thrombus to catch (e.g., between the tube 678 and the interior of the connector 624).

[0307] A foot pedal 651 has a base 653 and a pedal 655 that is coupled to the base 653 and movable or activatable by application of the foot of a user. The pedal 655 can be spring-loaded and compressible by application of a moment or a compressive force, or can instead comprise a membrane switch. The pedal 655, when activated, can in some embodiments toggle on and off, and in other embodiments can be activatable when a force, a pressure, or a moment is applied, and inactivated when the force, pressure, or moment is not applied. A first cable 661 carries signals from the foot pedal 651 to the pump 612 via a plug 665 that is connected to an input jack 667. A second cable 663 carries signals from the foot pedal 651 to the peristaltic pump 608 via a plug 669 that is connected to an input jack 671. In some embodiments, activation of the pedal 655 by the foot of a user starts the operation of the pump 612 and starts the operation of the peristaltic pump 608 at the same time. In some embodiments, activation of the pedal 655 by the foot of a user starts the operation of the peristaltic pump 608, and then starts the operation of the pump 612, with a slight delay after the peristaltic pump 608 is started. The delay is useful to assure that some aspiration, or a significant amount of aspiration, is being applied to the aspiration lumen 604 prior to the injection of pressurized fluid (e.g., saline) through the injection lumen 610. Thus, blood vessels or other vasculature in the vicinity of the open distal end 605 are spared any injection of fluid from a high pressure jet, as it is instead aspirated through the aspiration lumen 604.

[0308] In addition, in some embodiments, activation of the pedal 655 by the foot of a user during the operation of the pump 612 and the peristaltic pump 608 stops the operation of the pump 612 and the operation of the peristaltic pump 608 at the same time. In other embodiments, a delay can be applied, for example, such that the pump 612 is stopped, and then the peristaltic pump 608 is stopped slightly afterwards. The length of the delays described can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. The operation (on/off) of the pump 612 and/or peristaltic pump 608 via the foot pedal 651 allows hands-free activation, enabling a single user the manipulate the aspiration catheter 602 and guidewire 648 with both hands. The location of the foot pedal 651 can be tactfully found with the foot of the user, while the user maintains visual contact with the patient, and/or any monitors, or even other medical personnel.

[0309] In other embodiments, the foot pedal 651 can be replaced by another type of switch, including, but not

limited to a toggle on/off push button or hand switch, an audio-activated switch (voice activated, clap activated, click activated), an optical switch (beam/light sensor for hand or foot interruption), or any other kind of switch that can be activated by medical personnel. The switch can be remote (e.g., in a control room) or can be located near the procedural area. The switch can also be a sterile switch or sterilizable for location on a sterile area.

[0310] In some cases, the activation and deactivation (turning on and off) of the aspiration flow applied by the peristaltic pump 608 on the aspiration lumen 604 can be done by leaving the peristaltic pump 608 in a running condition, while the user opens and closes the stopcock 654. In other embodiments, the stopcock can be replaced by a pinch valve (not shown) to open or compress the extension tubing 638. The pinch valve can be operable by a foot switch or by a push button (on/off).

[0311] The controller 684 also monitors and controls several device safety functions, which include over pressure detection, air bubble detection, and vacuum or negative pressure charge. An additional pressure transducer 615 carried on the connector 624 monitors pressure (i.e. injection pressure), and senses the presence of air bubbles. Alternatively, or in conjunction, an optical device 617 can be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed by the pump 612 to produce that particular pressure. Consequently, if the electric current required by pump 612 exceeds a preset limit, the controller 684 will disable the pump 612 by cutting power to it. Air bubble detection can also be monitored by monitoring the electrical current required to drive the pump 612 at any particular moment. In order for a pump 612 to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump 612 or connecting system (including the aspiration lumen 604 of the aspiration catheter 604 and the tubing set 664). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. A sufficient volume of liquid is needed proximally to flush any finite amount of air through. The controller 684 monitors the pump 612 current for any abrupt downward change that can indicate that air has entered the system. If the rate of drop is faster than a preset limit, the controller 684 will disable the pump 612 by cutting power to it until the problem is corrected.

[0312] The aspiration catheter 602 of FIG. 48 is illustrated as having pressurized fluid injection through injection lumen 610. However, other embodiments of the aspiration system 600 exist in which the aspiration catheter 602 is replaced by a standard aspiration catheter, not having an injection lumen.

[0313] As an alternative to collecting the aspirated material in a blood bag, blood bottle, or the canister 658, aspirated components (blood, thrombus, saline, slurry, etc.) can be placed into a reinfusion device, such as a Stryker ConstaVac (CBCII) Blood Conservation System, or a Haemonetics OrthoPAT Orthopedic Perioperative Autotransfusion System. In some embodiments, the canister 658, itself, can comprise the reinfusion device. Returning at least some of the aspirated blood to the patient via reinfusion helps to diminish what is one of the inherent drawbacks to aspiration, blood loss.

[0314] In some embodiments, the blood can be cooled prior to being injected. In some embodiments, the blood can be heated prior to being injected. In some embodiments, other drugs can be added to the blood prior to it being inserted. In some cases, the blood can be diluted with saline, to decrease its viscosity, or decrease its hematocrit. This can

allow for decrease hemolysis to occur. In some cases, blood collected in the canister 658, or blood coming from the extension tube 638, can even be used as donor blood, to infuse into a different patient.

[0315] In some embodiments, an additional or alternate sensor can be used to monitor flow conditions for the notification of the user, including, but not limited to: a Doppler sensor, an infrared sensor, or a laser flow detection device. In some embodiments, an externally-attached (non-contact) Doppler sensor can be employed. In some embodiments, an infrared sensor or a laser flow detection device can be employed around the extension tubing 638. The alternate sensor (e.g., flow sensor, etc.) can be located at a number of different locations along the aspiration path, including on or in the extension tube 638, either proximal to or distal to the rotatable head 630 of the peristaltic pump 608.

[0316] FIG. 49 illustrates an aspiration catheter 700 having an elongate shaft 702, and with a radiopaque marker band 704 attached to the distal end 706 of the shaft 702. The shaft 702 defines an aspiration lumen 708 having an open distal end 710. An injection tube 712 having a distal end 714 is capped off with a microfabricated cap 716. The microfabricated cap 716 has an inner cylindrical cavity 718 configured for placing over the distal end 714 of the injection tube 712. An outer cylindrical surface 720 at the distal end 714 of the injection tube 712 is sealingly coupled to the microfabricated cap 716 at the inner cylindrical cavity 718, so that the injection lumen 722 of the injection tube 712 is closed and sealed at the distal end 714 to resist a high pressure. The outer cylindrical surface 720 can be bonded to the microfabricated cap 716 at the inner cylindrical cavity 718 by at least one of an adhesive, an epoxy, a weld (e.g., ultrasonic weld, or other fusing of materials), or a solvent. Alternatively, a circumferential seal (thin elastomeric ring) can be interposed between the outer cylindrical surface 720 and the microfabricated cap 716 at the inner cylindrical cavity 718 to create a seal, and a friction fit. The microfabricated cap 716 can comprise a number of different materials, including polymers or metals. The microfabricated cap 716 can be constructed by a number of different processes, including: micromachining, micro injection molding, three-dimensional printing, photolithography, shadow masking, etching, or microforming. These processes include additive processes and subtractive processes. An orifice 730 is formed in a wall 732 of the injection tube 712 and has a similar function to the orifice 674 of FIG. 48. High pressure fluid is forced out of the orifice 730 and into the aspiration lumen 708 (arrow) because the distal end 714 of the injection tube 712 is sealed.

[0317] An outer surface 724 of the injection tube 712 is bonded to an inner surface 726 of the aspiration lumen 708 with an adhesive 728 (or epoxy, or other joining means). The injection tube 712 is bonded at a particular rotational orientation with respect to the aspiration lumen 708 such that the orifice 730 is oriented toward an opposing surface 734 in the aspiration lumen 708. An unbonded section 736 extends a significant portion of the length of the aspiration catheter 700 in the proximal direction, thus allowing for enhanced flexibility and trackability. The center of the orifice 730 can be located a distance  $d_2$  from the proximal end of the microfabricated cap 716, such as between about 0.05 mm and about 10.00 mm so that a jet emanating from the orifice 730 clears the microfabricated cap 716. The center of the orifice 730 is located a distance  $d_1$  from the open distal end 710 of the aspiration lumen 708 such that the distal end of the microfabricated cap 716 does not extend from the aspiration lumen 708. However, in some embodiments, the

microfabricated cap can be configured to extend from the aspiration lumen 708, as long it does not have any sharp leading features.

[0318] FIG. 50 illustrates an aspiration catheter 740 having an elongate shaft 742, and with a radiopaque marker band 744 attached to the distal end 746 of the shaft 742. The shaft 742 defines an aspiration lumen 748 having an open distal end 750. An injection tube 752 having a distal end 754 is capped off with a microfabricated cap 756. The microfabricated cap 756 has an inner cylindrical cavity 758 configured for placing over the distal end 754 of the injection tube 752. An outer cylindrical surface 760 at the distal end 754 of the injection tube 752 is sealingly coupled to the microfabricated cap 756 at the inner cylindrical cavity 758, so that the injection lumen 762 of the injection tube 752 is closed and sealed at the distal end 754 to resist a high pressure. A reinforcement ring 795 is fit into the injection lumen 762 of the injection tube 752 at the distal end 754 to reinforce the distal end 754 and allow for higher strength seal. The reinforcement ring 795 can also be configured to allow a friction fit seal. The reinforcement ring can comprise a high strength metallic material such as stainless steel, or a rigid polymer. The outer cylindrical surface 760 can be bonded and/or sealed to the microfabricated cap 756 at the inner cylindrical cavity 758 by any of the methods or materials described in relation to the aspiration catheter 700 of FIG. 49. The microfabricated cap 756 can comprise any of the materials and be formed by any of the processes described in relation to the microfabricated cap 716 in FIG. 49. An orifice 770 is formed in a wall 772 of the injection tube 752 and has a similar function to the orifice 674 of FIG. 48. High pressure fluid is forced out of the orifice 770 and into the aspiration lumen 748 because the distal end 754 of the injection tube 752 is sealed.

[0319] An outer surface 764 of the injection tube 752 is bonded to an inner surface 766 of the aspiration lumen 748 with an adhesive 768 (or epoxy, or other joining means). The injection tube 752 is bonded at a particular rotational orientation with respect to the aspiration lumen 748 such that the orifice 770 is oriented toward an opposing surface 774 in the aspiration lumen 748. The adhesive 768 bond extends a significant portion of the length of the aspiration catheter 740 in the proximal direction.

[0320] FIG. 51 illustrates an aspiration catheter 701 having an elongate shaft 703, and with a radiopaque marker band 705 attached to the distal end 707 of the shaft 703. The shaft 703 defines an aspiration lumen 709 having an open distal end 711. An injection tube 713 having a distal end 715 is capped off with a microfabricated cap 717. The distal end 715 is necked down from the rest of the injection tube 713 by a heating and/or tensile stretching process to create a smaller outer diameter of the distal end 715. The microfabricated cap 717 has an inner cylindrical cavity 719 configured for placing over the reduced diameter distal end 715 of the injection tube 713. An outer cylindrical surface 721 at the distal end 715 of the injection tube 713 is sealingly coupled to the microfabricated cap 717 at the inner cylindrical cavity 719, so that the injection lumen 723 of the injection tube 713 is closed and sealed at the distal end 715 to resist a high pressure. The smaller diameter of the distal end 715 and the inner cylindrical cavity 719, allow for a relatively higher strength bond, because of the thereby increased hoop strength of the distal end 715. The outer cylindrical surface 721 can be bonded and/or sealed to the microfabricated cap 717 at the inner cylindrical cavity 719 by any of the methods or materials described in relation to the aspiration catheter 700 of FIG. 49. The microfabricated

cap 717 can comprise any of the materials and be formed by any of the processes described in relation to the microfabricated cap 716 in FIG. 49. An orifice 731 is formed in a wall 733 of the injection tube 713 and has a similar function to the orifice 674 of FIG. 48. High pressure fluid is forced out of the orifice 731 and into the aspiration lumen 709 because the distal end 715 of the injection tube 713 is sealed.

[0321] An outer surface 725 of the injection tube 713 is not bonded to an inner surface 727 of the aspiration lumen 709. Instead, the microfabricated cap 717 is bonded to the inner surface 727 with an adhesive 729 (or epoxy, or other joining means). An unbonded section 737 of the injection tube 713 extends a significant portion of the length of the aspiration catheter 701 in the proximal direction, thus allowing for enhanced flexibility and trackability. The microfabricated cap 717 is bonded such that the injection tube 713 is held at a particular rotational orientation with respect to the aspiration lumen 709 such that the orifice 731 is oriented toward an opposing surface 735 in the aspiration lumen 709.

[0322] FIG. 52 illustrates an aspiration catheter 741 having an elongate shaft 743, and with a radiopaque marker band 745 attached to the distal end 747 of the shaft 743. The shaft 743 defines an aspiration lumen 749 having an open distal end 751. An injection tube 753 having a distal end 755 is capped off with a microfabricated cap 757. The microfabricated cap 757 has an inner cylindrical cavity 759 which includes a proximal portion 799 configured for placing over the distal end 755 of the injection tube 753. An outer cylindrical surface 761 at the distal end 755 of the injection tube 753 is sealingly coupled to the microfabricated cap 757 at the inner proximal portion 799 of the cylindrical cavity 759, so that the injection lumen 763 of the injection tube 753 is sealed to resist a high pressure. The outer cylindrical surface 761 can be bonded and/or sealed to the microfabricated cap 757 at the proximal portion 799 of the inner cylindrical cavity 759 by any of the methods or materials described in relation to the aspiration catheter 700 of FIG. 49. The microfabricated cap 757 can comprise any of the materials and be formed by any of the processes described in relation to the microfabricated cap 716 in FIG. 49. An orifice 771 is an exit of a distal portion 797 of the inner cylindrical cavity 759 that communicates with the proximal portion 799. The inner cylindrical cavity 759 in FIG. 52 has a curved shape, but can alternatively form an L-shape, or make take a 45° angle with respect to the longitudinal axis of the aspiration catheter 741. The angle can vary between 45° and 135°. The orifice 771 is formed in a wall 773 of the microfabricated cap 757 and has a similar function to the orifice 674 in FIG. 48. High pressure fluid is forced through the inner cylindrical cavity 759, out of the orifice 771, and into the aspiration lumen 749 because the distal end 755 of the injection tube 753 is sealed.

[0323] An outer surface 765 of the injection tube 753 is bonded to an inner surface 767 of the aspiration lumen 708 with an adhesive 769 (or epoxy, or other joining means). The injection tube 753 is bonded at a particular rotational orientation with respect to the aspiration lumen 749 such that the orifice 771 is oriented toward an opposing surface 775 in the aspiration lumen 749. An unbonded section 777 extends a significant portion of the length of the aspiration catheter 741 in the proximal direction, thus allowing for enhanced flexibility and trackability. One or more of the individual features of the aspiration catheters 700, 740, 701, 741 of FIGS. 49-52 can be rearranged to create other new embodiments. The individual features each allow the production of a small diameter aspiration catheter capable of tracking into

distal vasculature, such as the vasculature of the head and neck, and also provide for aspiration including high pressure forced injection.

[0324] FIGS. 53-56 illustrate an insertable injection tube 920, and a method for using it in a patient. The patient is not shown, for simplicity, and the devices are shown in a straight configuration, but in use, it is common for the devices to be tracked through tortuosities of a patient's vasculature. In FIG. 53, a microcatheter 924 is configured for tracking into the neurovasculature of a patient, including the Circle of Willis and the cerebral arteries. The term "microcatheter" is used loosely to describe any catheter used for tracking into the neurovasculature. A larger catheter with similar design elements is possible, whether it can be used in the Circle of Willis or not. The microcatheter 924 can be incorporated as a component of an aspiration system 922 (FIGS. 54-56), or can be a standard microcatheter purchased separately by a user. The microcatheter 924 comprises a shaft 926 having a proximal end 928 and a distal end 930, with a lumen 932 extending through the shaft 926. A luer hub 934 (e.g., female luer connector) is sealingly attached to the proximal end 928 of the shaft 926. The microcatheter 924 can have a distal radiopaque marker (not shown), which is allied in a similar manner to the radiopaque marker bands 704, 744, 705, 745 in the aspiration catheters 700, 740, 701, 741 of FIGS. 49-52. A connector 936 includes a male luer 938 for connecting to the luer hub 934, and can include a valve 940, which can comprise a Touhy-Borst or the equivalent. The sideport 942 of the connector 936 can include a female luer for connecting to the male luer 650 of the extension tube 638 of the system 600 described in detail in relation to FIG. 48. In FIG. 53 a user tracks the microcatheter 924 over a guidewire 944 into the blood vessels that are the region of interest. In some cases, the region of interest can be one of the cerebral arteries or other arteries in the vicinity, where a thrombus 946 (FIG. 54) is causing a thromboembolic stroke in the patient.

[0325] In FIG. 54, the user removes the guidewire 944 and inserts the insertable injection tube 920 through the Touhy-Borst 940 and into the connector 936 and the lumen 932 of the microcatheter 924. The insertable injection tube 920 can include a microfabricated cap 948, as described in any of the embodiments of FIGS. 49-52, or can comprise an alternative configuration. However, the insertable injection tube 920 at the minimum comprises a high strength hollow tube 952 which can comprise stainless steel, nickel-titanium alloy, polyimide, or other high strength materials having sufficient column strength to be inserted through the lumen 932 of the microcatheter 924. The microfabricated cap 948 includes an orifice 950 configured to provide a jet of pressurized fluid, similar to the orifice 771 of the microfabricated cap 757 in FIG. 52. In FIG. 55, the user advances the insertable injection tube 920 further through the lumen 932 of the microcatheter 924, toward the distal end 930. A stop 954 is bonded to the outside of the high strength hollow tube 952 and has a front face 956 configured to butt up against a proximal face 958 of the connector 936 when the center of the orifice 950 is located at the preferred distance (e.g.,  $d_1$ , as in FIG. 49) from the distal end of the microcatheter 924. The insertable injection tube 920 can be provided with different models, each having a different length between the front face 956 and the center of the orifice 950, and each configured to be used with a particular length of microcatheter 924, or a particular model of microcatheter 924, or a particular microcatheter 924 model/connector 936 model combination. In some embodiments, the connector 936 can be a component of the insertable injection tube 920, and

instead of the Touhy-Borst 940, can instead be permanently sealed and coupled to the high strength hollow tube 952 at a proximal region. Thus, the coupling of the male luer 938 to the luer hub 934 provides the longitudinal stop that controls the  $d_1$  distance.

[0326] It may not always be possible to track an aspiration catheter 602 having high pressure injection forced aspiration capabilities (FIG. 48) into the neurovasculature, because of the smaller diameters and tortuosities of the vessels. Thus, the insertable injection tube 920 allows a microcatheter 924 to be converted into a forced aspiration catheter. Thus, forced aspiration can occur in very distal locations, and locations that are distal to significant tortuosity, where normally microcatheters are the preferred access means. The small diameter insertable injection tube 920 is capable of being inserted through the lumen 932 of a microcatheter 924 after the microcatheter 924 is inserted into the region of interest. In alternative procedures and alternative embodiments of a system, a microcatheter 924 being inserted over a guidewire 944 can be replaced by a flow-directed catheter having a lumen configured for placement of the insertable injection tube 920 being inserted to the region of interest without a guidewire.

[0327] FIG. 57 illustrates a particular distal configuration of a distal end 913 of the insertable injection tube 920. This configuration allows the microfabricated cap 948 and orifice 950 to be controllably and repeatedly inserted through the lumen 932 of the microcatheter 924 such that the orifice is automatically oriented and the one or more jets emanating from the orifice 950 (or one or more orifices 950) are directed against an opposite wall 929 in the lumen 932 of the microcatheter 924. The microfabricated cap 948 has a distal taper 960, that can comprise a fillet or a bevel, or other type of lead-in shape. The purpose of the distal taper 960 is to facilitate the insertion into the connector 936, the luer hub 934, or the lumen 932 (FIG. 54), and to ease the advancement of the microfabricated cap 948 through the lumen 932, especially when the shaft 926 is in a tortuous condition. A spline loop 962 is coupled to the microfabricated cap 948 and can be formed from a wire, such as stainless steel or cobalt-chromium-nickel-molybdenum, or can comprise a superelastic material, such as a nickel-titanium alloy. The spline loop 962 is configured to have a diameter that is slightly less than, equal to, or slightly greater than the diameter of the lumen 932 of the microcatheter 924. Turning to FIG. 58, a first end 921 of the spline loop 962 is bonded into a circumferential groove 923 in the microfabricated cap 948. There is a gap 925 between the first end 921 and a second end 927 of the spline loop 962, which allows space for the two ends 921, 927 to approach each other, and thus the diameter of the spline loop 962 to be forced smaller, for example, by stress placed on the spline loop 962 from the wall around the lumen 932 of the microcatheter 924. Because the rotational orientation between the spline loop 962 and the microfabricated cap 948 are fixed in relation to each other (by the bonding of the first end 921 into the groove 923), the orifice 950 remains oriented toward an opposite wall 929 in the lumen 932. The spline loop 962 is located at a different longitudinal position on the microfabricated cap 948 than the orifice 950, and thus, the spline loop 962 does not block or deflect the jet emanating from the orifice 950. In this embodiment, the spline loop 962 is slightly distal to the orifice 950, though in other embodiments, it can instead be located proximally. In other alternative embodiments, the spline loop 962 (or any analogous structure) can actually be used to at least somewhat deflect the jet emanating from the orifice 950, with the purpose of

changing the shape or direction of the jet, for instance, deflecting it at least partially in a proximal longitudinal direction. In these alternative embodiments, therefore, it can actually be desired to have the spline loop 962 located at substantially the same longitudinal location as the orifice 950. In some embodiments, the microfabricated cap 948 can be replaced by a simple plug (e.g., having at least some male portion plugging the lumen), into which similar features are formed, for example by drilling or skiving.

[0328] FIG. 59, the spline loop 962 is replaced by a spline ring 933, which is attached to the high strength hollow tube 952 instead of to the microfabricated cap 948. The spline ring 933 is formed from a flat wire (stainless steel or nickel-titanium alloy, or other) or from a stiff polymeric strip (polyimide or other stiff polymer), and has a shape somewhat like the number "6," extending between a first end 935 and a second end 937. A first loop portion 939 is configured to extend around the high strength hollow tube 952 for bonding thereon, and a second loop portion 941 serves the same purpose as the spline loop 962 of FIGS. 57-58, to guide the microfabricated cap 948 and to rotationally orient the orifice 950 within the lumen 932. Other spline shapes can alternatively be used which also serve to maintain the microfabricated cap 948 against the wall on one side of the lumen 932, and/or serve to resist rotation between the shaft 926 of the microcatheter 924 and either the high strength hollow tube 952 or the microfabricated tip 948 (whichever of the two includes the orifice 950). The spline loop 962 or the spline ring 933 can each be made from a radiopaque material, or can include a radiopaque material as a base, or plating or coating. Thus, during a procedure, it will be easier to visualize on x-ray or fluoroscopy the movement of the orifice 950 down the lumen 932 of the microcatheter 924. The microfabricated cap 948 can also or can alternatively comprise a radiopaque material or radiopaque coating or plating. The insertable injection tube 920 in the embodiments presented, is configured to be removable from the lumen 932 of the microcatheter 924, so that the microcatheter 924 can be subsequently used for one of its other functions (delivering embolic coils or embolic materials, drugs, replacing the guidewire 944 or even aspirating through the empty lumen 932). In alternative embodiments, the orifice 950 of the microfabricated cap 948 can be used to inject drugs or other materials into the vasculature, for example, by stopping or avoiding any vacuum or negative pressure placed on the proximal end of the lumen 932.

[0329] FIGS. 60-63 illustrate a method for treating a patient using the aspiration system 600 of FIG. 48, using aspiration catheter 602, or any of the alternative aspiration catheters 700, 740, 701, 741. Alternatively, the method can be accomplished using the aspiration system 922, or using the insertable injection tube 920 with a standard single lumen catheter, such as a microcatheter 924, a guiding catheter, or a guide sheath (long sheath). In all of these systems, the pump 612 and the peristaltic pump 608 as described in FIG. 48 can be utilized. In FIG. 60, an aspiration catheter 602 has been tracked into a blood vessel 943 (e.g., using a guidewire 648) and is advanced so that the open distal end 605 is adjacent the proximal end 945 of a thrombus 947. In some cases, aspiration utilizing the high pressure injection from the pump 612 through the tubing set 664 combined with distal-to-proximal flow impulse imparted on the extension tube 638 by the peristaltic pump 608 are not enough to cause the thrombus 947 to be sufficiently aspirated into the open distal end 605 and into the aspiration lumen 604 so that it can be macerated and aspirated. At times, the cause for this is that a space 949

distal to the thrombus 947 acts as a relative vacuum and pulls on the thrombus with a force (e.g., distally, away from the aspiration catheter 602), thus making it difficult to aspirate the thrombus. Though the blood vessel 943 is shown in a relatively normal state, at time the blood vessel can have become collapsed because of lack of blood pressure from occlusion by the thrombus 947. Other times, some of the thrombus 947 can have significantly solid or semi-solid portions that impede the ability to flow from a distal to proximal direction.

[0330] A user has encountered this condition while attempting to aspirate through operation of the pump 612 and peristaltic pump 608, and the aspiration catheter 602 is inserted and advanced into the blood vessel 943 as shown in FIG. 60. The user then can use a technique with the aspiration system 600 to alleviate the substantially no flow condition. In FIG. 61, the user advances the aspiration catheter 602 so that the open distal end 605 of the aspiration lumen 604 is distal to the thrombus 947. The advancement of the open distal end 605 of the aspiration catheter 602 through or past the thrombus 947 can be done without using a guidewire 648, but in certain instances, the guidewire 648 will need to be used to cannulate and pass through or past the thrombus 947 and then to track the aspiration catheter 602.

[0331] In FIG. 62, the user operates the pump 612 to inject fluid, while the peristaltic pump 608 is not being operated. Thus, pressurized fluid (e.g., heparinized saline, or saline mixed with a thrombolytic drug) is injected through the injection lumen 610 of the tube 678, through the orifice 674, into the aspiration lumen 604, and then out the open distal end 605 (arrows) and into the space 949 in the blood vessel 943. This occurs because there is no aspiration through the aspiration lumen 604, and the stopped peristaltic pump 608 acts as a closed valve, with one of the rollers 632 compressing the compressible portion 637 of the extension tube 638. The injection of the fluid increases the fluid volume of the space 949, and by doing so, is able to also increase its internal pressure, thus neutralizing the prior relative vacuum effect caused by the space 949. There is now flowable material in the space 949, such that aspiration using the peristaltic pump 608 with the pump 612 can allow maceration and aspiration of the thrombus 947 to begin (by now turning on the peristaltic pump 608). The aspiration catheter 602 can also be retracted as shown in FIG. 63, to better contact the thrombus 947 and to increase the percentage of thrombus 947 being aspirated. This can be continued until all or at least a clinically significant portion of the thrombus 947 is aspirated.

[0332] Returning to FIG. 62, in certain cases, such as thromboembolic stroke, the downstream tissue may not be receiving sufficient flow because of the occlusion caused by the thrombus 947. The user can run the fluid from the fluid source 679 through a cooling system, such as a heat exchanger or thermoelectric cooler 951 (FIG. 48) through which the tubing set 664 can run, and by which the fluid can be cooled. Additionally, an extracorporeal circuit 953 (FIG. 62) can be attached to the tubing set 664, so that blood removed from the patient (e.g., via a femoral artery, femoral vein, or jugular vein sheath 955) is added to the fluid from the fluid source 679, so that there is some oxygenated blood being injected into the space 949, some which can potentially feed downstream tissue with oxygen or nutrients. The cooled fluid (saline, blood, or saline plus blood) can additionally reduce the metabolic demands of the downstream tissue by actively cooling it. The inventors have demonstrated that using a pump 612 that utilizes a removable cartridge having a piston, hemolysis can be maintained at an

acceptably low value during this sort of injection and mixing of blood with the injected saline, from a mixture that includes about 10% blood, to a mixture that includes about 80% blood.

[0333] FIGS. 64-65 illustrate a method for treating a patient using the aspiration system 600 of FIG. 48, but incorporating an aspiration catheter 957 having a translatable injection tube 959. The aspiration catheter 957 has an elongate shaft 963 having an aspiration lumen 965 with a proximal end 971 and an open distal end 961. The translatable injection tube 959 has an injection lumen 973 having a proximal end 975 and a distal end 977. The distal end 977 is coupled to a microfabricated cap 979 having an orifice 981, such that pressurized fluid injected through the injection lumen 973 exits from the orifice 981, as in the orifice 771 in FIG. 52. At a high enough injection pressure, the fluid can emanate from the orifice 981 in a jet. Alternatively, the distal end 977 of the injection lumen 973 can be plugged or capped, and there can be an orifice formed in the wall of the injection tube 959, as in FIGS. 49-51. The pump 612 and the peristaltic pump 608 as described in FIG. 48 can be utilized. In FIG. 64, the aspiration catheter 957 has been tracked into a blood vessel 943 (e.g., using a guidewire 648) and is advanced so that the open distal end 961 is adjacent the proximal end 945 of a thrombus 947. A proximal female luer connector 983 is coupled to the injection lumen 973, and configured to couple to the male luer/distal end 670 of the tubing set 664. A filter 985 can be interposed between the female luer connector 983 and the male luer 670, to filter out particulate (FIG. 65). The filter has a proximal female luer 987 and a distal male luer 989. The filter 985 can be used with any of the embodiments described herein, in which fluid can be injected (intentionally or not) into the bloodstream of a patient.

[0334] As described, in some cases, aspiration utilizing the high pressure injection from the pump 612 through the tubing set 664 combined with distal-to-proximal flow impulse imparted on the extension tube 638 by the peristaltic pump 608 are not enough to cause the thrombus 947 to be sufficiently aspirated into the open distal end 961 and into the aspiration lumen 965 so that it can be macerated and aspirated. A stiff tube 991 is bonded coaxially over the injection tube 959 at a proximal length, or the injection tube 959, itself, can be made stiff proximally. The stiff tube 991 and/or the female luer connector 983 and/or the attached filter 985 can be gripped by the user, such that the user is able to advance the stiff tube 991 and the injection tube 959, in turn, distally, such that the microfabricated cap 979 and the orifice 981 are translated distally, through the thrombus 947 and into the space 949 distal to the thrombus 947. In some cases, being translated distally into a distal portion of the thrombus 947 can be sufficient. A dynamic seal 993 (o-ring, quad ring, etc.) can be sealed over the stiff tube 991 at all longitudinal positions of the stiff tube 991. Once the orifice 981 is located within the space 949, the pump 612 is operated without the operation of the peristaltic pump 608 (or with a significantly low setting of the peristaltic pump), such that fluid is injected through the injection lumen 973 and out the orifice 981, into the space 949.

[0335] The injection of the fluid increases the fluid volume of the space 949, and by doing so, is able to also increase its pressure, thus neutralizing the prior relative vacuum effect from the space 949. There is now flowable material within the space 949 such that aspiration using the peristaltic pump 608 with the pump 612 can allow maceration and aspiration of the thrombus 947 to begin (by now turning on the peristaltic pump 608). The shaft 963 of the catheter 957 can

also be advanced and retracted during aspiration, to increase the percentage of thrombus 947 being aspirated. In addition, the injection tube 959 can be advanced or retracted, in relation to the catheter. The orifice 981 can be adjusted to an appropriate position inside the aspiration lumen 965, or even slightly outside the aspiration lumen 965. This can be continued until all or at least a clinically significant portion of the thrombus 947 is aspirated. As described, in relation to certain ischemic conditions caused by the thrombus 947, including stroke, the user can run the fluid from the fluid source 679 through a cooling system, such as a heat exchanger or thermoelectric cooler 951 (FIG. 48) through which the tubing set 664 can run, and by which the fluid can be cooled. Additionally, an extracorporeal circuit 953 (as in FIG. 62) can be attached to the tubing set 664, so that blood removed from the patient (e.g., via a femoral artery, femoral vein, or jugular vein sheath 955) is added to the fluid from the fluid source 679, so that there is some oxygenated blood being injected into the space 949, some which can potentially feed downstream tissue. The cooled fluid (saline, blood, or saline plus blood) can additionally reduce the metabolic demands of the downstream tissue.

[0336] FIGS. 66-69 illustrate a method for treating a patient using the aspiration system 600 of FIG. 48, but incorporating an aspiration catheter 967 having a translatable injection tube 969. The aspiration catheter 967 has an elongate shaft 995 having an aspiration lumen 997 with a proximal end 999 and an open distal end 2066. The translatable injection tube 969 has an injection lumen 2068 having a proximal end 2070 and a distal end 974. The distal end 974 has a distal orifice 2072, such that pressurized fluid injected through the injection lumen 2068 exits from the orifice 2072, as in FIG. 69. At a high enough injection pressure, the fluid can emanate in a jet. The pump 612 and the peristaltic pump 608 as described in FIG. 48 can be utilized. Turning to FIG. 68 and FIG. 70, an occluder 976 comprising an elongate shaft 978, and a handle 980 at its proximal end 984, has an elastomeric occlusion element 982 coupled to its distal end 986 by a connection member 988. The occlusion element 982 can comprise a circular ring or a spheroid or ovoid, and be formed of any elastomeric material, such as silicone, or thermoplastic elastomers. The occlusion element 982 has a diameter that is slightly larger than the diameter of the injection lumen 2068, and is configured to significantly occlude flow distally to its particular longitudinal position within the injection lumen 2068. The position shown in FIG. 70 shows the occlusion element 982 occluding the injection lumen 2068 at a longitudinal position that is distal to a side orifice 990 in the wall 992 in the injection tube 969. Thus, when the occluder 976 is in the position shown in FIGS. 68 and 70, the orifice 2072 is blocked by the occlusion element 982, and pressurized fluid flows through the side orifice 990 (curved arrow, FIG. 70). The connection member 988 can comprise a radiopaque material. A radiopaque marker 994 attached to the injection tube 969 can be viewed on x-ray or fluoroscopy along with the radiopaque connection member 988 to assess the particular relative longitudinal position of the occlusion element 982 with respect to the side orifice 990. If desired, the radiopaque marker 994 can be located just proximal to the side orifice 990, though it is shown just distal to the side orifice 990 in FIG. 70. If the occlusion element 982 is retracted as shown in FIG. 71, and the occluder 976 removed, as shown in FIG. 69, injection of fluid through the injection lumen 2068 can exit the orifice 2072. The size of the side orifice 990 can be made small enough such that, when the occluder 976 is removed, most of the fluid injected

exists the orifice 2072, due to the fact that there is more resistance through the side orifice 990 than through the orifice 2072. Thus, with the injection tube 969 in a particular longitudinal position in relation the shaft 995, either injection through the orifice 2072 and into the space 949, or injection through the side orifice 990 and into the aspiration lumen 997 of the aspiration catheter 967 can be selected, using the occluder 976.

[0337] FIG. 72 illustrates an additional or alternative embodiment and step, that can be used in conjunction with the systems and steps of FIGS. 66-69. A blocking member 996 includes an elongate shaft 998, which can be a larger diameter proximally and a smaller diameter distally. The blocking member 996 also includes a spiral blocking element (or feature) 899 at its distal end and a handle 897 at its proximal end. The blocking member 996 can be constructed of any of the or can include embodiments or features described in relation to blocking members described in the co-owned PCT Pub. No. PCT/US2018/029196 to Incuvate, LLC, filed Apr. 24, 2018 and published Nov. 1, 2018 as WO 2018/200566 A1, which is hereby incorporated by reference in its entirety for all purposes. The blocking element 899 is configured to be placed down the injection lumen 2068 and delivered out of the orifice 2072 and into the space 949, as shown in FIG. 72, to catch potential distal emboli, and protect downstream tissue (brain tissue, heart tissue, etc.). In some embodiments, the blocking element 899 can be attached to the distal end of the occluder 976, so that they are combined into a single component. Thus, the occluding described in relation to FIGS. 68-71 can occur along with the distal protection/blocking described in relation to FIG. 72.

[0338] An alternative mode of using the aspiration system 1400' of FIG. 38 is shown in FIG. 73. The controller 1484 is programmed or programmable to command the peristaltic pump 1408 to operate bidirectionally, such that the rotatable head 1430 rotates in a back-and-forth manner, as shown in double-ended, curved arrow 1701. The back-and-forth rotation can create a "regurgitate" mode for thrombus that has been pulled into the aspiration lumen 1404' of the aspiration catheter 1402'. The controller 1484 can also be configured to shut down the pump 1412 while the peristaltic pump 1408 is in the "regurgitate" mode. The automatic cycling, by continual reversal of the motor, for example, allows the thrombus to be further macerated by the repetitive pulling and pushing cycles. The controller 1484 can be configured to perform a certain number of cycles and then to switch back to the aspiration direction (first rotational direction 1436 of FIG. 38) to fully remove the thrombus.

[0339] Using FIG. 36 as an example, but applying the description globally, in any of the embodiments described utilizing the peristaltic pump 1408, an alternative operation mode is possible, wherein the peristaltic pump 1408 can be run backwards (opposite of the first rotational direction 1436), so that it is causing at least some of the fluid within the extension tubing lumen 1444 and/or the aspiration lumen 1404 of the aspiration catheter 1402 to be injected out of the open distal end 1405 of the aspiration lumen 1404. For example, if the aspiration catheter 1402 is removed from the patient, material (thrombus, emboli, other clogged material) can be emptied out the open distal end 1405, prior to reusing the aspiration catheter 1402. In another use, with the aspiration catheter 1402 inside the vasculature, the proximal end 1442 of the extension tube 1438 can be placed into a container filled with contrast media or a lytic drug, or other drug, the peristaltic pump 1408 can then be run backwards to inject the contrast media, or drug into the vasculature of

the patient. Thus, an additional injection site or the detaching of a luer connection is not required.

[0340] In another alternative operation mode, the peristaltic pump 1408 is stopped, or caused to be stopped by the controller 1484, and a lytic drug is used as the fluid source 1479. The pump 1412 is then used for pulsing lytic into the patient's vasculature (e.g., at or near a thrombus) through the open distal end 1405 of the aspiration lumen 1404, via the high pressure injection lumen 1410 of the tube 1478. By shutting off the peristaltic pump 1408, the injection through the injection lumen 1410 (and out the orifice 1474) allows the lytic drug to be sent out the open distal end 1405, into the vasculature of the patient.

[0341] FIG. 75 illustrates an aspiration system 2400 comprising an aspiration catheter 2402 comprising an elongate shaft 2401 including an aspiration lumen 2404 having an open distal end 2405 and a proximal end 2406 configured to couple to a peristaltic pump 2408. The peristaltic pump 2408 is a roller pump having a base 2426, a pressure shoe 2428 carried by the base 2426, and a rotatable head 2430, rotatably coupled to the base 2426, and carrying two or more rollers 2432a-d. The rollers 2432a-d are arrayed around a perimeter 2434 of the rotatable head 2430. The rotatable head 2430 is configured to be rotatable in at least a first rotational direction 2436 with respect to a rotational axis 2499. The rotatable head 2430 can be rotated by a motor 2497, either directly, or with a gear train 2495. The peristaltic pump 2408 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 2408 can alternatively, or additionally be powered by a power cord 2493 configured to connect to a power supply. An extension tube 2438 having a distal end 2440 and a proximal end 2442, and having a lumen 2444 extending therethrough, is hydraulically coupled to the proximal end 2406 of the aspiration lumen 2404 via a connector 2424. The extension tube 2438 can be supplied (e.g., sterile) with the aspiration catheter 2402, or can be packaged and supplied separately. A Touhy-Borst seal 2446 is couplable and decouplable to the connector 2424 (e.g., via luer connections 2750, 2752) and is configured to be loosened/opened to allow the insertion of a guidewire 2448 through the connector 2424 and the aspiration lumen 2404. The aspiration lumen 2404 can thus be used to track the aspiration catheter 2402 over the guidewire 2448 through a subject's vasculature. The Touhy-Borst 2446 can be tightened to seal over the guidewire 2448, to maintain hemostasis. Other types of seals can be incorporated in place of the Touhy Borst 2446, including a spring-loaded, longitudinally compressible and actuatable seal. The distal end 2440 of the extension tube 2438 is slipped over a first barb fitting 2754 of a y-connector 2756. A second extension tube 2760 has a distal end 2761 that is slipped over a second barb fitting 2758 of the y-connector 2756. A third extension tube 2762 has a proximal end 2763 that is slipped over a third barb fitting 2764 of the y-connector 2756. The second extension tube 2760 and third extension tube 2762 are configured to operate under negative pressure without collapsing, and can comprise standard suction tubing. A distal end 2765 of the third extension tube 2762 is coupled to a female luer 2452 sideport of the connector 2424, either permanently by molding, or an adhesive bond or weld, or by an attachable and detachable connection, such as a luer 2766. The lengths of each of the second extension tube 2760 and third extension tube 2762 can be varied. In some embodiments, the third extension tube 2762 is relatively short, and the y-connector 2756 is configured to be located in a sterile area near the patient. In other embodiments, the third extension tube 2762

is configured to be relatively long, and the y-connector 2756 is configured to be located in a non-sterile area, away from the patient. The second extension tube 2760 is optional, as the third extension tube 2762 can have a much longer length and the pressure transducer 2416/aspiration monitoring system 2414 can be attached directly to the y-connector 2756 at the location of the barb fitting 2758. This connection can be direct, and so the barb fitting 2758 is also optional. With the longer third extension tube 2762, the y-connector 2756 and the aspiration monitoring system 2414 can both be close to a pump 2412, and can both reside in a non-sterile area. In some embodiments, the pressure transducer 2416 of the aspiration monitoring system 2414 can reside in-line with the extension tube 2438. For example, between the peristaltic pump 2408 and the aspiration catheter 2402.

[0342] In use, a compressible portion 2437 of the extension tube 2438 is placed within the pressure shoe 2428 of the peristaltic pump 2408 such that rotation of the rotatable head 2430 in the rotational direction 2436 causes fluid to be forced through the lumen 2444 of the extension tube 2438 from the distal end 2440 to the proximal end 2442, via compression of the compressible portion 2437 by the rollers 2432, one at a time. Optionally, an interface 2456 on the peristaltic pump 2408 is configured to allow a user to input information or commands to the peristaltic pump 2408 or other components of the system 2400. Otherwise, hardware or firmware can be pre-programmed with specific run parameters (motor speed, rotation speed, etc.). In some embodiments, there are only two rollers 2432. In other embodiments, there are three rollers 2432. In still other embodiments, as shown, there are four rollers 2432. As described, the rollers 2432 can be replaced by bumps or protrusions. The compressible portion 2437 can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible section 2437 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 2438, or in other embodiments, can comprise the entirety of the extension tube 2438 between the distal end 2440 and the proximal end 2442. The proximal end 2442 of the extension tube 2438 can be coupled to a hub 2457 of a canister 2458 having an interior 2460, to allow fluid 2459 passing through the extension tube 2438 to pass into the interior 2460. An additional hub 2462 in the canister 2458 can be left open (as shown) to allow the unfilled interior 2460 to match atmospheric pressure. Alternatively, the canister 2458 can be replaced by a bag, such as an empty infusion bag, configured for collecting aspirate therein.

[0343] The aspiration catheter 2402 additionally has a high pressure injection lumen 2410 for injecting saline from a pump 2421 comprising a syringe 2466, for example, via a high pressure pump 2412. The high pressure pump 2412 comprises a power injector having a motor 2479 configured to drive a lead screw 2468. In some embodiments, the motor 2479 is configured to drive the lead screw 2468 in a clockwise direction and in a counter-clockwise direction. The lead screw is coupled to a plunger 2489 within the syringe 2466. The syringe 2466 has a large bore 2491, and a large internal volume, and the motor 2479 is configured to enable large torques to generate high injection pressures within the syringe 2466. In some embodiments, the pump 2421 and the peristaltic pump 2408 can be housed within a single enclosure. In some embodiments, the pump 2412 and the peristaltic pump 2408 can be housed within a single enclosure. In some embodiments, the pump 2412, pump 2421, and the peristaltic pump 2408 can be housed within a single enclosure.

[0344] A tubing set 2464 is coupled to the syringe 2466. The pump 2412 includes a controller 2484 configured to vary the speed of the motor 2479 in an oscillating or variable manner to force the saline (flow) in an oscillating or variable manner through the injection lumen 2410 of the aspiration catheter 2402. In some embodiments, a controller 2484 is configured to operate the motor 2479 at a first motor speed at an initiation of a first injection cycle and to then adjust to a second motor speed at a time within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed. Thus, a general performance target can be quickly reached, and then adjusted to be maintained. In some embodiments, the first motor speed is between 1.5 and 3.5 times greater than the second motor speed. In some embodiments, the first motor speed is between 2 and 3 times greater than the second motor speed. In some embodiments, the first motor speed is 3.5 times to 20 times greater than the second motor speed, or 8 times to 12 times greater, or 9 to 11 times greater. In some embodiments, the second motor speed is configured to act as the main motor speed throughout the first injection cycle. Thus, the initiation of injection at the first motor speed quickly brings the injection to the chosen performance parameters and/or primes the system, and the change to the second motor speed serves to maintain these parameters, and to minimize overshoot. In some embodiments, after the motor speed is brought to the second, lower speed, the oscillation of the flow can be initiated. The tubing set 2464 further has a distal end 2470 (which can include a male luer) which is configured to hydraulically couple to the injection lumen 2410 via a female luer 2472. In use, injected saline is forced through the injection lumen 2410 by the pump 2412 and exits an orifice 2474 at a distal end 2476 of the injection lumen 2410. The injection lumen 2410 can extend within a separate tube 2478 (injection tube) that is substantially entirely within the shaft 2401. In some embodiments, the tube 2478 is attached to the internal wall of the shaft 2401 only at a distal end portion 2403. The injection tube 2410 can also be attached to the shaft 2401 at its proximal end. Thus, the free-floating nature of the remainder of the tube 2478 within the aspiration lumen 2404 or within the majority of the aspiration lumen 2404 increases the flexibility and trackability of the shaft 2401. The high pressure saline is forced through the injection tube 2478 and out the orifice 2474, causing a variable or oscillating (flow rate or flow velocity). The jet is aimed within the aspiration lumen 2404, just proximal the open distal end 2405 which can create a Venturi effect that forces blood or thrombus that is external and adjacent the open distal end 2405 into the aspiration lumen 2404. The combination of the operation of the peristaltic pump 2408 and the jet created by the high pressure saline cause the maceration of thrombus, and the movement/flow of material (saline/blood/macerated thrombus/small pieces of thrombus) through the aspiration lumen 2404 from the open distal end 2405 to the proximal end 2406, through the female luer 2452 of the connector 2424, and through the lumen 2444 of the extension tube 2438 from its distal end 2440 to its proximal end 2442, and finally into the interior 2460 of the canister 2458. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system 2400. Blood vessels can include peripheral blood vessels, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

[0345] Variability in injection flow rate, flow velocity, and/or flow back pressure of the jet can provide a high maximum shear rate, to break up and macerate thrombus or

other material, but without the injection of too high a volume of saline (or other fluid). Thus, the saline can be saved, and will not need to be changed as frequently, nor will the cost be as high. In some cases, a disrupted, non-laminar flow can be created by the variability and the higher maximum shear rate, and can serve to keep the lumens of the devices and tubing patent and flowing. Furthermore, larger pressure gradients can be achieved, allowing for a higher likelihood of the initiation of thrombus in a blood vessel to be pulled or forced into the open distal end 2405 of the aspiration lumen 2404 of the aspiration catheter 2402.

[0346] An aspiration monitoring system 2414 comprising a pressure transducer 2416 can be coupled, for example, proximal to the connector 2424 and/or proximal to the proximal end 2406 of the aspiration lumen 2404 of the aspiration catheter 2402, such that the pressure transducer 2416 is hydraulically coupled to the aspiration lumen 2404. In the aspiration system 2400 of FIG. 75, the aspiration monitoring system 2414 is spaced a distance from the y-connector 2756 by a relatively long second extension tube 2760 (or alternatively by a relatively long third extension tube 2762, as in the aspiration system 2100 of FIG. 74) such that the aspiration monitoring system 2414 resides in a non-sterile area. Thus, the aspiration monitoring system 2414 can be set up, prepped, calibrated, and operated by a technologist, sales representative, nurse, or other medical personnel that has not “scrubbed” and thus does not need to maintain sterility. For example, the aspiration monitoring system 2414 can be located near the pump 2412, or on the same table as the pump 2412. The aspiration monitoring system 2414 can include any of the features described in relation to the other aspiration monitoring systems 48, 62, 78, 900, 1216, 1270, 1414 disclosed herein. Signals from the pressure transducer 2416 are carried on an electric cable 2480 to an input 2482 of the pump 2412. As described, the controller 2484 within the pump 2412 is configured to control the operation of the pump 2412, including motor 2479, but the controller 2484 can also be configured to control the operation of the peristaltic pump 2408, via a cable 2486, or wirelessly. The controller 2484 can comprise a microcontroller. The controller 2484 can alternatively be located within the peristaltic pump 2408, or can be located at another location. Control using signals of measured pressure from the pressure transducer 2416 adds an additional safety element to the system 2400. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Unallowably high pressures can also be quickly identified, protecting the motor 2479 of the pump 2412 from burnout or overheating danger. The integrity of the tube 2478 is also protected, e.g., avoiding unnaturally high pressures that could lead to burst.

[0347] The in the aspiration catheter 2402, the female luer 2452 is located distally on the connector 2424 from the female luer 2472. Thus, aspirated blood/thrombus/saline enters the female luer 2452 without ever having to contact interior irregularities 2425 (in geometry, shape) within the connector 2424, that can otherwise cause flow resistance, or cause thrombus to catch (e.g., between the tube 2478 and the interior of the connector 2424).

[0348] A hand switch 2411 comprises an on/off button 2419 pushably carried on a housing 2423. Signals (e.g., “on” or “off”) from the hand switch 2411 are carried by a cable 2431, but can alternatively be carried wirelessly (e.g., to the controller 2484). An additional pressure transducer 2427, within the lumen 2444 can be utilized to sense the pressure within the lumen 2444. In some embodiments, the pressure

transducer 2427 is built into the hand switch 2411. Alternatively, the pressure transducer 2416 can be utilized for this purpose. Signals from the transducer 2427 or from the transducer 2416 are carried by the cable 2431 or the cable 2480, respectively. However, the signals can alternatively be delivered wirelessly. Thus, control of the system 2400 is available to a user who is in proximity to the hand switch 2411. The hand switch 2411 can be configured to be movable to different locations on and along the extension tube 2438 for the convenience of the user. The control of the system 2400 via the hand switch 2411 can be configured to include turning the pump 2412 on or off, turning the peristaltic pump 2408 on or off, increasing or decreasing the speed of either or both of the pumps 2412, 2408, or even controlling the flow oscillator 2420 (introduced further on). Thus, the button 2419 can in some embodiments comprise a plurality of buttons.

[0349] Alternatively, or additionally to the hand switch 2411, is a foot pedal 2451. The foot pedal 2451 has a base 2453 and a pedal 2455 that is coupled to the base 2453 and movable or activatable by application of the foot of a user. The pedal 2455 can be spring-loaded and depressible by application of a moment or a compressive force, or can instead comprise a membrane switch. The pedal 2455, when activated, can in some embodiments toggle on and off, and in other embodiments can be activatable when a force, a pressure, or a moment is applied, and inactivated when the force, pressure, or moment is not applied. A first cable 2461 carries signals from the foot pedal 2451 to pump 2412 via a plug 2465 that is connected to an input jack 2467. In some embodiments, activation of the pedal 2455 by the foot of a user starts the operation of the pump 2412 and starts the operation of the peristaltic pump 2408 at the same time, as a signal through the first cable 2461 is received by the controller 2484, which commands the pump 2412 to start and, via the cable 2486, commands the peristaltic pump 2408 to start. In some embodiments, activation of the pedal 2455 by the foot of a user starts the operation of the peristaltic pump 2408, and then starts the operation of the pump 2412, with a slight delay after the peristaltic pump 2408 is started. The delay is useful to assure that some aspiration, or a significant amount of aspiration, is being applied to the aspiration lumen 2404 prior to the injection of pressurized fluid (e.g., saline) through the injection lumen 2410. Thus, blood vessels or other vasculature in the vicinity of the open distal end 2405 are spared any injection of fluid from a high pressure jet, as it is instead aspirated through the aspiration lumen 2404, along with thrombus or blood. In some embodiments, the plug 2465 of the foot pedal 2451 can include a resistor 2759, and the pump 2412 can include an identification circuit 2757 configured to read the resistance value of the resistor 2759. For example, the resistor 2759 can complete a partial Wheatstone bridge carried on the identification circuit 2757, such that the pump 2412 can recognize the foot pedal 2451, and operate accordingly. Alternatively, the resistor 2759 can reside in the foot pedal 2451 itself, instead of the plug 2465. The cable 2461 can provide the electrical connection to the resistor 2759 in that particular case. Alternatively, the resistor 2759 can be replaced by an RFID chip that is configured to be powered and read by the identification circuit 2757.

[0350] In addition, in some embodiments, activation of the pedal 2455 by the foot of a user during the operation of the pump 2412 and the peristaltic pump 2408 stops the operation of the pump 2412 and the operation of the peristaltic pump 2408 at the same time. In other embodiments, a delay can be applied, for example, such that the pump 2412 is

stopped, and then the peristaltic pump 2408 is stopped slightly afterwards. The length of the delays described can be between about 0.01 second and about 1.00 second, or between about 0.10 second and about 0.25 second. The operation (on/off) of the pump 2412 and/or peristaltic pump 2408 via the foot pedal 2451 allows hands-free activation, enabling a single user the manipulate the aspiration catheter 2402 and guidewire 2448 with both hands. The location of the foot pedal 2451 can be tactiley found with the foot of the user, while the user maintains visual contact with the patient and/or any monitors, or even other medical personnel. Alternatively, a second cable 2463 carries signals from the foot pedal 2451 directly to the peristaltic pump 2408 via a plug 2469 that is connected to an input jack 2471. Thus, the operation of the foot pedal 2451 can be configured to control the operation of the peristaltic pump 2408 in embodiments, for example, in which there is no cable 2486. However, in the embodiment of FIG. 75, which includes the cable 2486, the cable 2463 is not required. Alternatively, the controller 2484 is configured to monitor a signal from the pressure transducer 2416, and initiate the injection (e.g., through the pump 2421) when a particular threshold negative pressure is indicated from the pressure transducer signal. The controller 2484 can be further configured or programmed to shut the entire system down, if the threshold negative pressure is not sensed within a particular amount of time (e.g., 1 to 3 seconds, 1.5 to 2.5 seconds, etc.). In these cases, the user can be notified visually, audibly, or tactiley: "no suction."

[0351] In other embodiments, the foot pedal 2451 can be replaced by another type of switch, including, but not limited to a toggle on/off push button or hand switch, an audio-activated switch (voice activated, clap activated, click activated), an optical switch (beam/light sensor for hand or foot interruption), or any other kind of switch that can be activated by medical personnel. The switch can be remote (e.g., in a control room) or can be located near the procedural area. The switch can also be a sterile switch or sterilizable for location on a sterile area. As mentioned, in some embodiments, the pressure transducer 2416 of the aspiration monitoring system 2414 can reside in-line with the extension tube 2438. For example, it can be located between the peristaltic pump 2408 and the aspiration catheter 2402.

[0352] In some cases, the activation and deactivation (turning on and off) of the aspiration flow applied by the peristaltic pump 2408 on the aspiration lumen 2404 can be done by leaving the peristaltic pump 2408 in a running condition, while the user opens and closes a stopcock 1454 (e.g., FIG. 36, 39, or 73), which can in some embodiments be incorporated into the system 2400 of FIG. 75. In some embodiments, the controller 2484 controls the initiation of both the peristaltic pump 2408 and the pump 2412 at substantially the same time. In some embodiments, the controller 2484 controls the initiation the peristaltic pump 2408 and, following a particular delay, the initiation of the pump 2412. The delay can be within the ranges previously described.

[0353] The controller 2484 also monitors and controls several device safety functions, which include over pressure detection, air bubble detection, and vacuum or negative pressure charge. An additional pressure transducer 2415 carried on the connector 2424 monitors pressure (i.e. injection pressure), and senses the presence of air bubbles. Alternatively, or in conjunction, an optical device 2417 can be used to sense air bubbles. In one contemplated embodiment, the pump pressure is proportional to the electric current needed by the pump 2412 to produce that particular pressure. Consequently, if the electric current required by

pump 2412 exceeds a preset limit, the controller 2484 will disable the pump 2412 by cutting power to it. Air bubble detection can also be monitored by monitoring the electrical current required to drive the pump 2412 at any particular moment. For example, the electrical current can be monitored by a transducer. The controller 2484 is configured to calculate an injection pressure based at least in part on the measured electrical current. In order for a pump 2412 to reach high fluid pressures, there should be little or no air (which is highly compressible) present in the pump 2412 or connecting system (including the aspiration lumen 2404 of the aspiration catheter 2402 and the tubing set 2464). The fluid volume is small enough that any air in the system will result in no pressure being generated at the pump head. A sufficient volume of liquid is needed proximally to flush any finite amount of air through. The controller 2484 monitors the pump 2412 current for any abrupt downward change that can indicate that air has entered the system. If the rate of drop is faster than a preset limit, the controller 2484 will disable the pump 2412 by cutting power to it until the problem is corrected.

[0354] In some embodiments, a fluid level sensor 2473 is carried on the side of the canister 2458 and is configured to sense when the canister 2458 has approached or reached its full level. The fluid level sensor 2473 is configured to output a signal through a cable 2475 that is attached to via an input 2477 (plug/jack) at the pump 2412. The signal from the fluid level sensor 2473 can be received by the controller 2484 which can be configured to immediately stop the pump 2412 and, via cable 2486, the peristaltic pump 2408 at the same time, or with a delay therebetween, as previously described. The fluid level sensor 2473 can comprise an optical sensor, and the canister 2458 can have a clear wall, to allow the optical sensor to measure the reflection variations when fluid is not adjacently present or when fluid is adjacently present. Alternatively, the fluid level sensor 2473 can comprise a piezoresistive pressure sensor that is within the volume 2460 of the canister 2458 at the desired height that represents a "full" canister 2458. Other types of fluid sensors are also contemplated, including floats, strain gauges, laser sensors, ultrasonic sensors, or capacitive sensors. In each of these embodiments, a signal is sent wirelessly or through cable 2475 so that the peristaltic pump 1408 and/or pump 2412 can be shut down when a "full" level is reached.

[0355] In some embodiments, the peristaltic pump 2408 and the pump 2412 are combined into a single console. This allows for a smaller size that can be mounted on a standard IV pole. In some embodiments, a separate flow oscillator 2420 can provide additional variation in flow rate, flow velocity, and/or fluid pressure. In some embodiments, the separate flow oscillator 2420 can provide all of the variation in flow rate, flow velocity, and/or fluid pressure, while the pump 2421 does not. In these particular embodiments, the pump 2421 provides a constant flow rate, flow velocity, pressure differential, one its own, but the flow oscillator 2420 creates the variation or oscillation in flow. Cable 2486a can be configured to transfer signals between the controller 2484 and the flow oscillator 2420, thus allowing the controller 2484 to control the operation of the flow oscillator 2420. In other embodiments, the controller 2484 is configured to communicate with the flow oscillator 2420 (and/or other components) wirelessly.

[0356] FIG. 76 illustrates a detailed view of an injector syringe mechanism 1152 that combines elements similar to the pump 2421 comprising a syringe 2466 and the flow oscillator 2420 of the system 2400 of FIG. 75. The injector syringe mechanism 1152 is constructed with the required

power, and thus is driven by a motor 1124 having an armature 154 and a rotor 196. The shaft 156 of the motor 1124 is drivingly coupled to a threaded screw shaft 158 for rotation by the motor 1124. Threadedly engaging shaft 158 is a ball nut 160 which is prevented by pin 162 from rotating, but which is free to move axially along shaft 158, the pin 162 sliding in a guide slot 164 formed in a guide bar 166 supported in the housing 168 of the injector syringe mechanism 1152. The axial movement of ball nut 160 in response to rotation of threaded shaft 158 converts the rotary motion of the motor 1124 into linear motion. The ball nut 160 is connected to a piston tube 170 which moves with the ball nut 160 along the shaft 158. The outer end of the piston tube 170 is supported, during its linear motion, by a seal 172 secured in an opening 174 at one end of housing 168. The piston tube 170 abuts directly against a piston head support member 176, which, in turn, provides mechanical support for a rubber piston cap 178. A syringe barrel, or cartridge, 180 is mounted on the injector housing 168 by an internally threaded nut 182 adapted to engage external threads on the end of the housing 168. The nut 182 has a centrally located aperture 184 which receives the barrel 180, and a seal member 186, to permit an airtight fitting on the end of the housing 168. A flanged portion 188 is provided on the end of the barrel 180, and faces the housing, to facilitate a tight seal between sealing members 174 and 186 when nut 182 is tightened.

[0357] The internal diameter ID of the barrel 180 and the external diameter of piston 176 are selected to provide the clearance required to permit a flanged edge 190 of the rubber piston cap 178 to seal the interior of the syringe. It will be apparent that different sizes of syringes will require pistons having varying diameters, but the construction of this mechanism is such that the various sizes are easily connected to the injector drive mechanism. The aperture 184 in the nut 182 is sufficiently large to permit larger syringes than that illustrated, while by providing smaller diameter syringes with sufficiently large flanges, they can be used with this equipment as well. Piston member 176 and cap 178 can be driven in a forward direction (toward the right as viewed in FIG. 76) by piston tube 170 without any mechanical connection being made between the piston 176 and the tube 170. This arrangement is often used where it is essential to prevent reversal of the motion of the piston. Alternatively, piston 176 can be connected to piston tube 170 by means of screws 192, to permit both forward and reverse driving of the piston 176. Alternatively, any other type of latching mechanism can be incorporated to achieve the same effect. It will be apparent that forward motion of the piston 176 will expel fluid or any other matter within the barrel 180, such as saline 194 (or contrast media, or a mixture of saline and contrast media). If the piston 176 is attached to the piston tube 170, reverse driving can be used to fill the barrel 180.

[0358] The broken-away portion of motor 1124 illustrates, in addition to armature 154, the arrangement of the rotor 196. In operation, direct current is commutated to the armature conductors 1127, and the resultant alternating magnetic field interacts with the stationary magnetic field(s) of the rotor 196 to produce torque on shaft 156 in the chosen rotational direction (clockwise or counter-clockwise). Gears 198 and 2200 provide a mechanical linkage of known gearing ratio between the motor shaft 156 and tachometer generator 1122. The tachometer can in some embodiments be electronic, or can be electro-optical.

[0359] The injector syringe mechanism 1152 includes an output 1123 configured to be detachably hydraulically coupled to a proximal end 1133 of a tubing set 2464. The

flow oscillator 2420, aspiration catheter 2402, extension (aspiration) tube 2438, and peristaltic pump 2408 are shown generically in FIG. 76, but can include any of the embodiments described herein. In the following embodiments of the flow oscillator 2420, the flow oscillator 2420 can be used in series with the injector syringe mechanism 1152 to provide a variable flow rate, variable flow velocity, and/or variable pressure injection into the tubing set 2464, and into the high pressure injection lumen 2410 of the aspiration catheter 2402. The variability can in some embodiments comprise oscillation. In some embodiments, the injector syringe mechanism 1152 provides at least some of the configured variability. In other embodiments, only the flow oscillator 2420 provides the configured variability. The configured variability in either case can also include starting or stopping pumping, or reversing.

[0360] FIGS. 77-78 illustrate a flow oscillator 2420a on a tubing set 2464a, according to a first embodiment. The flow oscillator 2420a comprises a relief valve 2501. In some embodiments, there can be two or more relief valves 2501. The tubing set 2464a comprises an inflow tube 2500 and an outflow tube 2502. The inflow tube 2500, as shown in FIG. 76, is between the injector syringe mechanism 1152 and the flow oscillator 2420a, and hydraulically coupled to each. The outflow tube 2502 is between the flow oscillator 2420a and the aspiration catheter 2402, and hydraulically coupled to each. For example, a distal end 2504 of the inflow tube 2500 is bonded within a counterbore 2506 of a base 2508 of the flow oscillator 2420a. A proximal end 2510 of the outflow tube 2502 is bonded within a counterbore 2512 of the base 2508 of the flow oscillator 2420a. The ends 2504, 2510 of the tubes 2500, 2502 can be adhesively or epoxy bonded, or can be secured over barb fittings, or other equivalents. The base 2508 of the flow oscillator 2420a comprises a main flow passageway 2514 extending from a proximal end 2516 to a distal end 2518 of the base 2508. Normal injection flow is configured to pass through a lumen 2520 of the inflow tube, through the main flow passageway 2514 of the base 2508 of the flow oscillator 2420a, and through a lumen 2522 of the outflow tube 2502 (dashed arrows).

[0361] An inlet nozzle 2524 extends from a bifurcation 2526 transversely to the flow path (dashed arrows) of the flow passageway 2514. A valve seat 2528 is held by a holder 2530 valve seat shaft 2532. A compression spring 2533 is carried around the shaft 2532 and abuts a first stop 2535 on the shaft 2532 and a second stop 2537 within the interior 2529 of a bonnet 2531 that extends from the base 2508. The valve seat 2528 is shown sealed over an aperture 2534 of the inlet nozzle 2524 in FIG. 77, and is shown in an open condition in FIG. 78, where it is not sealed over the aperture 2534. The spring is selected and/or adjusted, such that a desired release pressure  $R_P$  is coordinated. When the pressure  $P_1$  is below the release pressure  $R_P$ , the spring 2533 maintains the valve seat 2528 in a sealing position over the aperture 2534. When the pressure  $P_2$  is increased to or above the release pressure  $R_P$ , the spring 2533 compresses sufficiently such that there is an opening of the valve seat 2528 in relation to the aperture 2534. See solid arrows in FIG. 78 which show excess fluid passing through a bypass passage 2536. The interior 2529 of the bonnet 2531 is sealed from the rest of the interior of the base 2508 by a structural seal 2538, which also can help to maintain a concentric relationship of the shaft 2532 and valve seat 2528 with the interior 2529 of bonnet 2531, and thus the aperture 2534. The top end 2540 of the shaft 2532 is able to longitudinally translate within a cap 2542 carried on the bonnet 2531. The shaft

**2532** moves through a hole **2544** at the end of the bonnet **2531**. In some embodiments, a user can remove the cap **2542** and manipulate the top end **2540** of the shaft **2532** (e.g., by turning it, unscrewing it, screwing it in, etc.) to adjust the effective spring constant of the spring **2533**, and thus dial in a different (lower or higher) release pressure  $R_p$ .

[0362] In a flow system in which the serial flow resistance due to the lumen **2522** of the outflow tube **2502** and the high pressure injection lumen **2410** of the aspiration catheter **2402** is lower than a critical flow resistance, the flow oscillator **2420a** will not significantly cause a variable pressure or variable flow rate (or flow velocity). Instead, a constant flow rate output by the injector syringe mechanism **1152**, when increased, will reach a maximum, when the pressure in the flow oscillator **2420a** is equal to the release pressure  $R_p$  of the relief valve. However, in a high resistance, high velocity jet system, such as an injection-assisted thrombectomy aspiration catheter, such as the aspiration catheter **2402**, the flow oscillator **2420a** will oscillate as the valve opens and closes, above and below, respectively, the release pressure  $R_p$  of the relief valve. The oscillation of the pressure and the resulting flow through the high pressure injection lumen **2410** can be adjusted by a user such that it has a frequency that is effective in optimizing an aspiration (e.g., thrombectomy) procedure. In some embodiments, this comprises a 3-8 Hz oscillation. In some embodiments, this comprises a 4-7 Hz oscillation. In some embodiments, this comprises a 5-6 Hz oscillation. In some embodiments, this comprises a 5 Hz oscillation. In some embodiments, the oscillation is sinusoidal, but in others it can be “clipped” or “pinned” in shape. The relief valve **2501** can be configured to cause the clipping or pinning, e.g., at the maximum of the injection pressure curve.

[0363] FIGS. 79-81 illustrate a flow oscillator **2420b** on a tubing set **2464b**, according to a second embodiment. The flow oscillator **2420b** comprises a proportional solenoid **2546**. The tubing set **2464b** comprises an inflow tube **2548** and an outflow tube **2550**. The inflow tube **2548**, is between the injector syringe mechanism **1152** and the flow oscillator **2420b**, and hydraulically coupled to each. The outflow tube **2550** is between the flow oscillator **2420b** and the aspiration catheter **2402**, and hydraulically coupled to each. For example, a distal end **2552** of the inflow tube **2548** is bonded within a counterbore **2554** of a base **2556** of the flow oscillator **2420b**. A proximal end **2558** of the outflow tube **2550** is bonded within a counterbore **2560** of the base **2556** of the flow oscillator **2420b**. The ends **2552**, **2558** of the tubes **2548**, **2550** can be adhesively or epoxy bonded, or can be secured over barb fittings, or other equivalents. The base **2556** of the flow oscillator **2420b** comprises a first main flow passageway **2562a** extending from a proximal end **2564** to a central portion **2566** of the base **2556**, and a second main flow passageway **2562b** extending from the central portion **2566** to a distal end **2568** of the base **2556**. Normal injection flow is configured to pass through a lumen **2570** of the inflow tube, through the first main flow passageway **2562a** of the base **2556** of the flow oscillator **2420b**, through the central portion **2566**, and through a lumen **2572** of the outflow tube **2550**. The central portion **2566** comprises a first transverse passage **2574**, a second transverse passage **2576**, and a connecting space **2578**.

[0364] A side projection **2580** includes a transverse cavity **2582** in which a solenoid valve **2584** is slidably contained. The solenoid valve **2584** is connected to a linearly actuatable shaft **2586** that is electromagnetically actuated by a solenoid **2588**. A stop **2590** in the central portion **2566** represents the fully closed position at which the sealing end **2592** of the

solenoid valve **2584** stops and fully seals off the first main flow passageway **2562a** from the second main flow passageway **2562b**. FIG. 79 illustrates the proportional solenoid **2546** in the fully closed (sealed) position. In this position there is no flow proceeding from the first transverse passage **2574** to the second transverse passage **2576**, because the connecting space **2578** is completely blocked by the sealing end **2592** of the solenoid valve **2584**. FIG. 80 illustrates the proportional solenoid **2546** in the partially close position. In this position, there is flow from the first transverse passage **2574** to the second transverse passage **2576**, but there is some flow resistance at the connecting space **2578**, due to its decreased space height. FIG. 81 illustrates the proportional solenoid **2546** in the fully open position. In this position, there is flow from the first transverse passage **2574** to the second transverse passage **2576**, with the least amount of resistance, because the connecting space **2578** is at its maximum space height.

[0365] The controller **2484** is configured to apply a variable (e.g., sinusoidal) voltage/current at the proportional solenoid **2546**, causing the solenoid valve **2584** to slide up and down in a variable manner with the changes in voltage/current, opening and closing the connecting space **2578**. In other configurations, the controller **2484** causes a variable operation of the proportional solenoid **2546** between the configuration of FIG. 80 and the configuration of FIG. 81, avoid the fully closed configuration of FIG. 79. In some embodiments, the controller **2484** causes a variable operation of the proportional solenoid **2546** between a first partially open configuration and a second partially open configurations. The resulting variable or oscillatory flow rate, flow velocity, and/or pressure delivers a variable jet in the aspiration catheter **2402**. The flow path is from the lumen **2570**, through the first main flow passageway **2562a**, through the first transverse passage **2574**, through the connecting space **2578**, through the second transverse passage **2576**, through the second main flow passageway **2562b**, and through the lumen **2572**. Then, the fluid is injected through the high pressure injection lumen **2410**, where its exits as a jet into the aspiration lumen **2404** of the aspiration catheter **2402**. The controller **2484** can be configured to receive a signal from the pressure transducer **2415**, or any pressure transducer that is hydraulically coupled to the system, for example to the lumen of the tubing set **2464b**.

[0366] The proportional solenoid **2546** can be configured to electrically adjust at a controlled frequency. The oscillation of the pressure and the resulting flow through the high pressure injection lumen **2410** can be adjusted by a user such that it has a frequency that is effective in optimizing an aspiration (e.g., thrombectomy) procedure. In some embodiments, this comprises a 3-8 Hz oscillation. In some embodiments, this comprises a 4-7 Hz oscillation. In some embodiments, this comprises a 5-6 Hz oscillation. In some embodiments, this comprises a 5 Hz oscillation.

[0367] FIG. 82 illustrates a block diagram of the injector syringe mechanism **1152** and flow oscillator **2420b/tubing set 2464b** of FIGS. 76 and 79-81. In this embodiment, the flow oscillator **2420b** comprises an iQ Valve, proportional solenoid **2546** (Melbourne, Florida, USA). A microvalve **2594** is coupled to the iQ Valve **2546** to control a leak rate (e.g., into the atmosphere **2595**). This in turn determines the actual pressure drop in the system. A pressure transducer **2415** and catheter **2402** are also illustrated.

[0368] FIGS. 83-84 illustrate a flow oscillator **2420c** on a tubing set **2464c**, according to a third embodiment. The flow oscillator **2420c** comprises a tubing pincher **2600** or compressor. The tubing set **2464c** comprises compressible tub-

ing 2602, at least at the portion that extends through the tubing pincher 2600. The tubing 2602, is between the injector syringe mechanism 1152 and the aspiration catheter 2402, and hydraulically coupled to each. The pincher 2600 comprises a first pinch rod 2604 and a second pinch rod 2606. The pinch rods 2604, 2606 each extend transversely to a pincher body 2608. The tubing 2602 of the tubing set 2646c is configured to be placed between the first pinch rod 2604 and the second pinch rod 2606. At least the first pinch rod 2604 is configured to be moveable by an internal motor or other mechanism 2610 to be moved along a y-axis in a positive and negative direction. The controller 2484 is configured to cause the first pinch rod 2604 to move sinusoidally back-and-forth, in a positive Y and negative Y direction. The rods 2604, 2606 are attached to connectors 2612, 2614 that are coupled to the body 2608. FIG. 83 illustrates the tubing 2602 in place between the pinch rods 2604, 2606 in the open, uncompressed position. The first pinch rod 2604 and its connector 2612 are moveably coupled to the body 2608 (upper arrow in FIG. 84). In some embodiments the second pinch rod 2606 is attached statically to the body 2608 (as in FIG. 84), and in other embodiments can also be moveable in relation to the body 2608 (alternative double arrow in FIG. 84). FIG. 84 illustrates the first pinch rod 2604 after having been moved by the motor/mechanism 2610 to a position that almost occludes the tubing 2602, but does not completely occlude the tubing. Thus, below a particular threshold fluid viscosity, the oscillation between the position of FIG. 83 and the position of FIG. 84 produces a non-clipped pressure wave to the fluid injected by the injector syringe mechanism 1152. In other embodiments, a clipped (on the high end) pressure wave can instead be created. In some embodiments, the oscillation comprises a 3-8 Hz oscillation. In some embodiments, it comprises a 4-7 Hz oscillation. In some embodiments, it comprises a 5-6 Hz oscillation. In some embodiments, it comprises a 5 Hz oscillation.

[0369] In some embodiments, the hand switch 2411, or the foot pedal 2451, or any other switch coupled to the pump 2421/syringe 2466 can be configured to change the effect of the injection of fluid from an oscillating manner to a non-oscillating manner. In some embodiments, the foot pedal 2451, or any other switch coupled to the pump 2421/syringe 2466, can be configured to change the effect of the injection of fluid from a non-oscillating manner to an oscillating manner. In some embodiments, the foot pedal 2451, or any other switch coupled to the pump 2421/syringe 2466 can be configured to change the effect of the injection of fluid from an oscillating manner to a damped oscillating manner, e.g., having damped or pseudo-damped oscillation. A pseudo-damped oscillation can be constructed and simulated by maintaining the frequency of the change in screw direction (counter-clockwise to clockwise and vice versa), but slowly decreasing the total number of turns of the screw in each direction while also decreasing the average and maximum rotational speed of the screw in each direction. The effect is a pressure wave that has an unchanged frequency, but a lower pressure differential amplitude. In some embodiments, the oscillation of the injection of the pump 2421/syringe 2466 comprises a 3-8 Hz oscillation. In some embodiments, it comprises a 4-7 Hz oscillation. In some embodiments, it comprises a 5-6 Hz oscillation. In some embodiments, it comprises a 5 Hz oscillation. In some embodiments, the oscillation is sinusoidal, but in others is can be “clipped” or “pinned” in shape.

[0370] Though not intended to be limiting, in some embodiments, the injection pressure of the pump 2421/

syringe 2466 can oscillate within a range that is between about 200 psi (13.6 atmospheres) and about 1500 psi (102.1 atmospheres). In some embodiments, the injection pressure of the pump 2421/syringe 2466 can oscillate within a range that is between about 600 psi (40.8 atmospheres) and about 800 psi (54.4 atmospheres). In some embodiments, the injection pressure of the pump 2421/syringe 2466 can oscillate within a range that is between about 600 psi (40.8 atmospheres) and about 700 psi (47.6 atmospheres), or that is between about 700 psi (47.6 atmospheres) and about 800 psi (54.4 atmospheres). In some embodiments, the injector is configured to pressurize the liquid such that the flow rate varies between about 20 ml/min and about 45 ml/min, or about 31 ml/min.

[0371] The flow oscillator 2420b of FIGS. 79-81 and the flow oscillator 2420c of FIGS. 83-84 can be configured so that occlusion and/or compression can never reach a “completely closed” state. In the case of the flow oscillator 2420b, this can be achieved mechanically, by the abutment 2413 shown in FIG. 85, that stops the solenoid valve 2584 from closing completely. The completely closed state can also be avoided by precision control of the controller 2484. Similar mechanical and/or electronic (controller) control can be maintained on the flow oscillator 2420c. In other embodiments, the tubing 2602 can comprise a highly compliant portion upstream (between the flow oscillator 2420c and the pump 2421), so that a temporary occlusion of the tubing 2602 caused by the pinch rods 2604, 2406 causes a temporary increase in interior volume of the tubing 2602, thus avoiding a catastrophic pressure increase.

[0372] FIG. 86 illustrates an aspiration system 2300 comprising an aspiration catheter 2302 comprising an elongate shaft 2301 including an aspiration lumen 2304 having an open distal end 2305 and a proximal end 2306 configured to couple to a peristaltic pump 2308. The aspiration lumen 2304 is similar to the aspiration lumen 2404 of the aspiration catheter 2402 of FIG. 75. The peristaltic pump 2308 is a roller pump having a base 2326, a pressure shoe 2328 carried by the base 2326, and a rotatable head 2330, rotatably coupled to the base 2326, and carrying two or more rollers, as shown in FIG. 75 (rollers 2432a-d). The rollers are arrayed around a perimeter of the rotatable head 2330. The rotatable head 2330 is configured to be rotatable in at least a first rotational direction 2336 with respect to a rotational axis. The rotatable head 2330 can be rotated by a motor 2397, either directly, or with a gear train. The peristaltic pump 2308 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The peristaltic pump 2308 can alternatively, or additionally be powered by a power cord 2393 configured to connect to a power supply 2332. An extension tube 2338 having a distal end 2340 and a proximal end 2342, and having a lumen 2344 extending therethrough, is hydraulically coupled to the proximal end 2306 of the aspiration lumen 2304 via a connector 2324. The extension tube 2338 can be supplied (e.g., sterile) with the aspiration catheter 2302, or can be packaged and supplied separately. In the embodiment shown in FIG. 86, the extension tube 2338 comprises a sterile portion 2338a and a non-sterile portion 2338b. A proximal end of the sterile portion 2338a comprises a connector 2388 and a distal end of the non-sterile portion 2338b comprises a connector 2390. Connector 2388 is configured to hydraulically couple to connector 2390. In alternative embodiments, the connectors 2388, 2390 can be replaced by a tube-to-barb connection. A Touhy-Borst seal 2346 is couplable and decouplable to the connector 2324 (e.g., via luer connections) and is configured to be loosened/opened to allow the insertion of a

guidewire 2348 through the connector 2324 and the aspiration lumen 2304. The aspiration lumen 2304 can thus be used to track the aspiration catheter 2302 over the guidewire 2348 through a subject's vasculature. The Touhy-Borst 2346 can be tightened to seal over the guidewire 2348, to maintain hemostasis. Other types of seals can be incorporated in place of the Touhy Borst 2346, including a spring-loaded, longitudinally compressible and actuatable seal. The distal end 2340 of the extension tube 2338 is slipped over a first barb fitting 2354 of a sideport 2352 of the connector 2324. A second extension tube 2363 has a distal end 2361 that is slipped over a second barb fitting 2365 of the connector 2324 and a proximal end 2367. The extension tube 2338 is configured to operate under negative pressure without collapsing, and can comprise standard suction tubing.

[0373] In use, a compressible portion 2337 of the extension tube 2338 is placed within the pressure shoe 2328 of the peristaltic pump 2308 such that rotation of the rotatable head 2330 in the rotational direction 2336 causes fluid to be forced through the lumen 2344 of the extension tube 2338 from the distal end 2340 to the proximal end 2342, via compression of the compressible portion 2337 by the rollers, in sequence. Optionally, a user interface 2356 on the peristaltic pump 2308 is configured to allow a user to input information or commands to the peristaltic pump 2308 or other components of the system 2300. Otherwise, hardware or firmware can be pre-programmed with specific run parameters (motor speed, rotation speed, etc.). In some embodiments, there are only two rollers. In other embodiments, there are three rollers. In still other embodiments, as shown, there are four rollers. In other embodiments, the rollers can be replaced by bumps or protrusions. The compressible portion 2337 can comprise silicone tubing, polyurethane tubing, polyvinyl chloride tubing, or other compressible tubing. The compressible section 2337 can be a relatively short section that is attachable to and detachable from the peripheral ends of the extension tube 2338 (e.g., non-sterile portion 2338b), or in other embodiments, can comprise the entirety of the non-sterile portion 2338b, or even the entirety of the extension tube 2338 between the distal end 2340 and the proximal end 2342. The proximal end 2342 of the extension tube 2338 is configured to be coupled to a hub 2357 of a canister 2358 having an interior 2360, to allow fluid passing through the extension tube 2338 to pass into the interior 2360. An additional hub 2362 in the canister 2358 can be left open (as shown) to allow the unfilled interior 2360 to match atmospheric pressure. Alternatively, the canister 2358 can be replaced by a bag, such as an empty infusion bag, configured for collecting aspirate therein. In some embodiments, a filter can be placed in line with the canister 2358, to specifically maintain thrombus and collect it, if desired.

[0374] The aspiration catheter 2302 additionally has a high pressure injection lumen 2310 for injecting saline from a pump 2321 comprising a syringe 2366, for example, via a high pressure pump 2312. The high pressure injection lumen 2310 is similar to the high pressure injection lumen 2410 of the aspiration catheter 2402 of FIG. 75. The high pressure pump 2312 comprises a power injector having an electric motor 2379 outputting rotation to a gearbox 2341 (e.g., gearbox), which is configured to change a rotational speed (faster or slower) and/or to change a torque (lower or higher). The output of the gearbox 2341 is configured to indirectly drive a ball nut 2343 (FIGS. 87-88) over a stationary (non-rotational) ball screw 2368 (e.g., via a belt drive configuration). The ball screw 2368 is shown within the ball nut 2343 by phantom lines, but the ball bearings are

not shown. In other embodiments, the ball nut 2343 and the ball screw 2368 can be replaced by a standard nut and leadscrew, or a half-nut and leadscrew. In the embodiment of FIGS. 87-88, the motor 2379 is configured to drive the ball nut 2343 in a clockwise direction and in a counter-clockwise direction. In other embodiments, the ball nut 2343 can be driven in a single direction. The ball screw 2368 is statically coupled to a plunger 2389 that is sealingly carried within a barrel 2373 of the syringe 2366 and configured to be displaced along a longitudinal displacement path within the bore 2391 of the barrel 2373. The barrel 2373 of the syringe 2366 has a large bore 2391, having a large internal volume, and the motor 2379 is configured to enable large torques to generate high injection pressures within the syringe 2366. In some embodiments, the pump 2321 and the peristaltic pump 2308 can be housed within a single enclosure. In some embodiments, the high pressure pump 2312 and the peristaltic pump 2308 (and the controller 2384) can be housed within a single enclosure. In some embodiments, the high pressure pump 2312, pump 2321, and the peristaltic pump 2308 (and the controller 2384) can be housed within a single enclosure. The aspiration catheter 2302 is configured to be placed through a guiding catheter, an introducer sheath, or through direct blood vessel puncture. The high pressure pump 2312 can be battery powered, and the battery (ies) can be rechargeable by wired or wireless means. The high pressure pump 2312 can alternatively, or additionally be powered by a power cord 2398 configured to connect to a power supply 2399.

[0375] A tubing set 2364 is coupled to the syringe 2366. The high pressure pump 2312 is coupled to a controller 2384 that is configured to vary the speed of the motor 2379 or to turn the motor 2379 on and/or off. The controller 2384 can also be configured to control the motor 2397 of the peristaltic pump 2308 in the same manner (vary speed, turn on, turn off). The high pressure pump 2312 is configured to automatically inject in an oscillating or variable manner to force the saline (flow) in an oscillating or variable manner through the injection lumen 2310 of the aspiration catheter 2302. In some embodiments, a controller 2384 is configured to operate the motor 2379 at a first motor speed at an initiation of a first injection cycle and to then adjust the motor 2379 to a second motor speed at a time period within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed. Thus, a general performance target can be quickly reached, and then adjusted to be maintained. In some embodiments, the first motor speed is between 1.5 and 5 times greater than the second motor speed. In some embodiments, the first motor speed is between 3 and 4 times greater than the second motor speed. In some embodiments, the first motor speed is 3.5 times to 20 times greater than the second motor speed, or 8 times to 12 times greater, or 9 to 11 times greater. In some embodiments, the second motor speed is configured to act as the main motor speed throughout the first injection cycle. Thus, the initiation of injection at the first motor speed quickly brings the injection to the chosen performance parameters and/or primes the system, and the change to the second motor speed serves to maintain these parameters, and to minimize overshoot. In some embodiments, after the motor speed is brought to the second, lower speed, the oscillation of the flow can be initiated, or a significant amount of oscillation can be initiated or increased.

[0376] In use, injected saline is forced through the injection lumen 2310 by the high pressure pump 2312 and exits an orifice (e.g., similar to orifice 2474 of FIG. 75) at a distal

end (e.g., distal end 2476 of FIG. 75) of the injection lumen 2310. The injection lumen 2310 can extend within a separate tube (injection tube) that is substantially entirely within the shaft 2301. In some embodiments, the tube is attached to the internal wall of the shaft 2301 only at a distal end portion. The injection tube 2349 can also be attached to the shaft 2301 at its proximal end. Thus, the free-floating nature of the remainder of the tube within the aspiration lumen 2304 or within the majority of the aspiration lumen 2304 increases the flexibility and trackability of the shaft 2301. The high pressure saline is forced through the injection tube 2349 and out the orifice, causing a variable or oscillating (flow rate or flow velocity). The oscillation is created by a flow oscillator 2420d (FIGS. 87-88). The jet is aimed within the aspiration lumen 2304, just proximal the open distal end 2305 which can create a Venturi effect that forces blood or thrombus that is external and adjacent the open distal end 2305 into the aspiration lumen 2304. The combination of the operation of the peristaltic pump 2308 and the jet created by the high pressure saline cause the maceration of thrombus, and the movement/flow of material (saline/blood/macerated thrombus/small pieces of thrombus) through the aspiration lumen 2304 from the open distal end 2305 to the proximal end 2306, through the female luer 2352 of the connector 2324, and through the lumen 2344 of the extension tube 2338 from its distal end 2340 to its proximal end 2342, and finally into the interior 2360 of the canister 2358. Thus, thrombus within a blood vessel of a subject can be macerated and removed by use of the system 2300. Blood vessels can include peripheral blood vessels, coronary blood vessels, or blood vessels within the head or neck of the subject, including carotid arteries or cerebral arteries.

[0377] Variability in injection flow rate, flow velocity, and/or flow back pressure of the jet can provide a high maximum shear rate, to break up and macerate thrombus or other material, but without the injection of too high a volume of saline (or other fluid). Thus, the saline can be saved, and will not need to be changed as frequently, nor will the cost be as high. In some cases, a disrupted, non-laminar flow can be created by the variability and the higher maximum shear rate, and can serve to keep the lumens of the devices and tubing patent and flowing. Furthermore, larger pressure gradients can be achieved, allowing for a higher likelihood of the initiation of thrombus in a blood vessel to be pulled or forced into the open distal end 2305 of the aspiration lumen 2304 of the aspiration catheter 2302.

[0378] An optional aspiration monitoring system 2314 comprising a pressure transducer 2316 is coupled, for example, proximal to the connector 2324 and/or proximal to the proximal end 2306 of the aspiration lumen 2304 of the aspiration catheter 2302, such that the pressure transducer 2316 is hydraulically coupled to the aspiration lumen 2304. In the aspiration system 2300 of FIG. 86, the aspiration monitoring system 2314 is carried on the connector 2324 with the pressure transducer 2316 within the interior of the connector 2324. The aspiration monitoring system 2314 can include any of the features described in relation to the other aspiration monitoring systems 48, 62, 78, 900, 1216, 1270, 1414, 2414 disclosed herein. Signals from the pressure transducer 2316 are carried on an electric cable 2380 to an input of the controller 2384. The controller 2384 is configured to control the operation of the high pressure pump 2312, including motor 2379, via a cable 2381, but the controller 2384 can also be configured to control the operation of the peristaltic pump 2308, via a cable 2386, or wirelessly. The controller 2384 can comprise a microcontroller. The controller 2384 can alternatively be located

within the peristaltic pump 2308, or can be located at another location. Control using signals of measured pressure from the pressure transducer 2316 adds an additional safety element to the system 2300. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. Alternatively, a pressure sensor can be added to the high pressure pump 2312, so that unallowably high pressures can also be quickly identified, protecting the motor 2379 of the high pressure pump 2312 from burnout or overheating danger. The integrity of the second extension tube 2363 and of the injection tube 2349 would thus also be protected, e.g., avoiding unnaturally high pressures that could lead to burst.

[0379] In the aspiration catheter 2302, the sideport 2352 is located distally on the connector 2324 from the second barb fitting 2365. Thus, aspirated blood/thrombus/saline enters the sideport 2352 without ever having to contact interior irregularities (in geometry, shape) within the connector 2324, that can otherwise cause flow resistance, or cause thrombus to catch (e.g., between the injection tube 2349 and the interior of the connector 2324).

[0380] A hand switch 2311 comprises an on/off button 2319 pushably carried on a housing 2323. Signals (e.g., "on" or "off") from the hand switch 2311 are carried by a cable 2331 to the controller 2384, but can alternatively be carried wirelessly (e.g., to the controller 2384). A main aspiration monitoring system 2800 comprises a pressure transducer 2801 (FIG. 95) which is carried by the housing 2323 for fluid contact with the lumen 2344 is utilized to sense the pressure (e.g., negative pressure) within the lumen 2344. In some embodiments, the pressure transducer 2801 is built into the hand switch 2311. The pressure transducer 2801 extends through a hole 2803 in the wall 2804 of the sterile portion 2338a or the extension tube 2338. The hole 2803 is in some embodiments sealingly filled with an adhesive, epoxy, or polymer 2806. Signals from the pressure transducer 2801 are carried by conductive wires 2802 within the cable 2331 to the controller 2384. However, the signals can alternatively be delivered wirelessly. Thus, control of the system 2300 is available to a user who is in proximity to the hand switch 2311. The hand switch 2311 is carried on the sterile portion 2338a, and is also provided sterile. The user can thus include a user that has "scrubbed" for a procedure. The hand switch 2311 is secured around the extension tube 2338 with a sheath 2805 that is sealed around the exterior of the extension tube 2338. In some embodiments, the sheath 2805 comprises shrink tubing. The hand switch 2311 can be configured to be located at different locations on and along the extension tube 2338 for the convenience of the user. The control of the system 2300 via the hand switch 2311 can be configured to include turning the high pressure pump 2312 (e.g., motor 2379) on or off, turning the peristaltic pump 2308 (e.g., motor 2397) on or off, increasing or decreasing the speed of either or both of the pumps 2312, 2308, or even controlling the flow oscillator 2420d. The button 2319 can in some embodiments comprise a plurality of buttons or other types of controls. Alternatively, or additionally to the hand switch 2311, a foot pedal, similar to the foot pedal 2451 of FIG. 75, can be utilized, having any or all of the structure and functionality of the foot pedal 2451. The controller 2384 can include any or all of the structure and functionality of the controller 2484 of FIG. 75. The pressure transducer 2801 is thus part of the main aspiration monitoring system 2800, which can include any of the features described in relation to the other aspiration monitoring systems 48, 62, 78, 900, 1216, 1270, 1414, 2414, 2314 disclosed herein. Control using signals of measured pressure from the pressure trans-

ducer 2801 adds an additional safety element to the system 2300. Additionally, a non-functional device (because of a leak, incomplete connection, incomplete priming, rupture, blockage) can be quickly identified. The integrity of the second extension tube 2363 and of the injection tube 2349 is also protected, e.g., avoiding unnaturally high pressures that could lead to burst.

[0381] The high pressure pump 2312 comprises a base 2701 having vertical side walls 2702, 2703, connected to and extending from the base 2701. The motor 2379 is mounted vertically onto the base 2701 via a motor mount 2704, or in other embodiments is coupled directly to the base 2701. The gearhead 2341 extends upward from the motor 2379, and the flow oscillator 2420d is coupled above the gearhead 2341. A housing 2705 encloses the coupling of the flow oscillator 2420d and the syringe 2366. The syringe 2366 injects through an output nozzle 2706, and a connector 2707 hydraulically couples to the nozzle 2706 to the proximal end 2367 of the second extension tube 2363, in a detachable manner.

[0382] The flow oscillator 2420d of the high pressure pump 2312 is shown in more detail in FIGS. 87-91. The stationary ball screw 2368 is coupled to a bi-directionally vertically-moveable slide 2709, via a horizontal pin 2710. The slide 2709 is carried on the back wall 2708. The back wall 2708 is connected to the base 2701. A transverse through hole 2711 extends through the ball screw 2368, and the horizontal pin 2710 engages the through hole 2711 to restrict rotation of the ball screw 2368. Thus, as the nut 2343 is turned, the ball screw 2368 is driven and caused to move up and down in unison with the slidable portion 2807 of the slide 2709 (double-headed arrow, FIG. 88). The nut 2343 is rotatably carried on the upper horizontal plate 2712 by a bearing 2715. The upper horizontal plate 2712 comprises a vertical through hole 2713 adjacent with and aligned with the internal thread 2714 of the nut 2343. Thus, as the motor 2379/gear head 2341 drive rotation of the nut 2343 via a timing belt 2729, the internal thread of the nut 2343 is engaged with and translates axially in relation to the external thread 2716 of the ball screw 2368.

[0383] In addition to the up or down driven motion actuated by the interaction between the nut 2343 and the ball screw 2368, the flow oscillator 2420d causes back-and-forth axial oscillation (e.g., up-and-down motion) via two circular bump plates or "ripple plates" 2717, 2718 (disks) as their relative rotational orientation is changed with respect to each other, also by the driving of the motor 2379. The general injection of the syringe 2366 is driven by the rotation of the nut 2343 with respect to the ball screw 2368. As the ball screw 2368 is driven upward, the plunger 2389 injects by decreasing the volume of the barrel 2373 of the syringe 2366 and increasing its internal pressure, thus configured to inject liquid (e.g., saline) from the barrel 2373. The output of the gearhead 2341 turns an output shaft 2719. The flow oscillator 2420d comprises a first bump plate disk 2717 that is statically coupled to the output shaft 2719 and is configured to rotate therewith and move vertically therewith. The flow oscillator 2420d further comprises a second bump plate disk 2718 that is statically coupled to the upper horizontal plate 2712 and is not configured to rotate. The first bump plate disk 2717 and the second bump plate disk 2718 each comprise a central hole 2720, 2721, respectively, that allows clearance of the output shaft 2719. The output shaft 2719 extends through the hole 2720 of the first bump plate disk 2717, and the first bump plate disk 2717 is configured to rotate in unison with the output shaft 2719. In some embodiments, the first bump plate disk 2717 is welded to the output

shaft 2719. In other embodiments, the first bump plate disk 2717 is secured to the output shaft 2719 by mechanical connectors, or adhesive or epoxy, or they are permanently screwed together or pinned together. The output shaft 2719 extends through the hole 2721 of the second bump plate disk 2718, and the output shaft 2719 is configured to freely rotate within the hole 2721. The output shaft 2719 is further secured to a first toothed pulley 2722 such that the output shaft 2719 and the first toothed pulley 2722 rotate in unison. The first toothed pulley 2722 comprises a cylindrical body 2723 having an axial hole 2724. The output shaft 2719 is configured to insert into the hole 2724. In some embodiments, the first toothed pulley 2722 is welded to the output shaft 2719. In other embodiments, the first toothed pulley 2722 is secured to the output shaft 2719 by mechanical connectors, or adhesive or epoxy, or they are permanently screwed together or pinned together. The first toothed pulley 2722 further comprises circumferentially-arrayed teeth 2725, for example four to 60 teeth, or six to 40 teeth, or 20 to 40 teeth, or four to ten teeth. A short pulley 2726 having circumferentially-arrayed teeth 2727 is secured to the upper end 2728 of the nut 2343. In some embodiments, the short pulley 2726 is welded to the nut 2343. In other embodiments, the short pulley 2726 is secured to the nut 2343 by mechanical connectors, or adhesive or epoxy, or they are permanently screwed together or pinned together. In some embodiments, the number of teeth 2727 of the short pulley 2226 can match the number of teeth 2725 of the first toothed pulley 2722. In other embodiments, the number of teeth 2727 of the short pulley 2226 can be greater or less than the number of teeth 2725 of the first toothed pulley 2722 in order to deliver an increased torque to the nut 2343, or to increase the rotational speed of the nut 2343, respectively. However, the speeds can be controlled partially or solely by the gear ratio of the gearhead 2341. The teeth 2725, 2727 can in some embodiments be replaced by or can include ther-between holes or spaces configured to engage teeth of a timing belt 2729. In an opposite alternative embodiment, the second bump plate disk 2718 is statically connected to the output shaft 2719 and configured to rotate in unison with it, and the first bump plate disk 2717 is statically connected to a stationary casing around the gearhead 2341. Thus, the rotation of the second bump plate disk 2718 in relation to the non-rotational first bump plate disk 2717 induces the axial motion imparted by the flow oscillator 2420d.

[0384] Returning to the embodiment of FIGS. 86-91, the timing belt 2729 is configured to engage with the teeth 2725, 2727 (or hole, spaces). The timing belt 2729 comprises a continuous 360° pathway, and can be configured to take an oval, elliptical, circular, or other path shape as it is engaged for turning in unison with the first toothed pulley 2722 and the nut 2343/short pulley 2226, via the teeth 2725, 2727 (or hole, spaces). In alternative embodiments, the timing belt 2729 is replaced by a continuous chain having a plurality of links, each link or some of the links configured to engage one of the teeth 2725, 2727.

[0385] A distal end 2730 of the ball screw 2368 comprises a transverse hole 2731. The plunger 2389 of the syringe 2366 comprises a rubber material, a thermoplastic elastomer, or another substantially elastic material. The plunger 2389 is carried by a rigid base 2732 having a transverse hole 2733. A pin 2734 is placed through the hole 2733 of the base 2732 and through the hole 2731 of the ball screw 2368. The pin 2734 and the pin 2710 provide general securing of the ball screw 2368 while allowing for some freedom of movement, such that the relationship between the external thread 2716 of the ball screw 2368 and the internal thread 2714 of

the nut 2343 is “sloppy” and is not over-constrained. Thus, galling between the threads 2716, 2714 is lessened, minimized, or avoided. In alternative embodiments, the securing can be a set screw, instead of the pin 2734.

[0386] Turning to FIGS. 89-91, as the first bump plate disk 2717 is rotated in unison with the output shaft 2719 by the motor 2379/gearhead 2341 in a first rotational direction 2735, a first axial surface 2736 of the first bump plate disk 2717 is caused to circumferentially slide over a second axial surface 2737 of the second bump plate disk 2718. In this embodiment, each of the surfaces 2736, 2737 are substantially similar to each other. FIG. 90 illustrates the surfaces facing each other in a minimum axial displacement configuration between the two surfaces 2736, 2737. As the first bump plate disk 2717 in the first rotational direction 2735, a maximum axial displacement configuration between the two surfaces 2736, 2737 (FIG. 91). Each of the two surfaces 2736, 2737 has a circumferential sawtooth path 2738 having a series of deepest portions 2739, in terms of an indentation into the disk 2717, 2718, and a series of maximum protrusion portions 2740. The deepest portions 2740 (e.g., depressions) and the maximum protrusion portions 2740 are interspersed between each other and are circumferentially arrayed. In the minimum axial displacement configuration of FIG. 90, the deepest portions 2739 of the first disk 2717 do not necessarily exactly match the maximum protrusion portions 2740 of the second disk 2718 (and the deepest portions 2739 of the second disk 2718 in relation to the maximum protrusion portions 2740 of the first disk 2717), but they are very similar to each other in terms of each of their circumferential positions. In contrast, as the first bump plate disk 2717 is rotated in relation to the second bump plate disk 2718 toward the maximum axial displacement configuration of FIG. 91, at the maximum axial displacement configuration the maximum protrusion portions 2740 of the first disk 2717 substantially match the maximum protrusion portions 2740 of the second disk 2718, thus causing the maximum axial displacement DispMAX. In a particular embodiment, there are 36 maximum protrusion portions 2740 on the first disk 2717 and 36 maximum protrusion portions 2740 on the second disk 2718. If the first disk 2717 is rotated at a rotational speed of 10 revolutions per minute (RPM) the complete back-and-forth cycles will occur at a frequency of six Hertz (Hz). In other words, there will be six slips between the maximum protrusion portions 2740 of the first disk 2717 and the maximum protrusion portions 2740 of the second disk 2718 each second. In some embodiments, the controller 2384 is configured to operate the system 2300 such that the back-and-forth cycles occur at a frequency of between about 0.5 Hz and about 10 Hz, or between about one Hz and about eight Hz. While these slips are occurring, the timing belt 2729 is driving the nut 2343 such that a continual axial displacement of the nut 2343 on the ball screw 2368 is also occurring. Thus, besides the injection of fluid (e.g., saline) from the syringe 2366, there is also a cyclic variance in both pressure and flow rate from the syringe, caused by the cyclic slips between the two disk surfaces 2736, 2737 (see time period C of graph in FIG. 94). Besides the general injection via the plunger 2389 being caused by the upward driving of the ball screw 2368 by the rotating nut 2343, there is the additional cyclic up-and-down motion of the nut 2343 itself, in unison with the upper horizontal plate 2712, which is caused by the axial displacement changed from the reaction between the first bump plate disk 2717 and the second bump plate disk 2718. In some embodiments, the upper horizontal plate 2712 is movably held on its periphery by one or more axial guides or slides

2771, 2772. The guides allow the up-and-down movement of the upper horizontal plate 2712, but at least partially confine or constrain it from side-to-side movement.

[0387] The controller 2384 is configured to control the operation of the high pressure pump 2312 to cause the high pressure pump 2312 to inject pressurized fluid in a pulsatile manner, utilizing the cyclic or sinusoidal variation in the axial displacement between the two surfaces 2736, 2737. The high pressure jet is applied in a pulsatile fashion to optimize the cutting ability of the jet on a piece of thrombus. For example, a portion of thrombus that is aspirated into the open distal end 2305 of the aspiration lumen 2304 of the aspiration catheter 2302 can be more readily severed by a pulsating jet, much in the manner that a reciprocating saw. The controller 2384 is configured to operate the high pressure pump 2312 to pressurize fluid through the injection lumen such that the one or more jets are pulsatile. The controller 2384 is also configured to operate the peristaltic pump 2308 to further aid that that pressurized fluid injected through the injection lumen causes the one or more jets to be pulsatile. In some embodiments, the controller 2384 can vary the motor 2397 speed of the peristaltic pump 2308 so that it varies in a cyclic or sinusoidal manner. Or, that it produces a cyclic or sinusoidal variance in the negative pressure that is provided by the operation of the peristaltic pump 2308.

[0388] An alternative aspiration system 2300' is illustrated in FIGS. 98-99. The aspiration system 2300' is similar in most aspects to the aspiration system 2300 of FIGS. 86-91, except that the cyclic up-and-down axial motion of the flow oscillator 2420d is provided by the nut 2343 alone, while the upper horizontal plate 2712 is maintained in a static state. The output of the gearhead 2775 is coupled to the output shaft 2719 by a weld 2775. The upper horizontal plate 2712 is secured to the housing by attachments 2773, 2774. The disks 2717, 2718 have a similar relative rotation and axial motion, but the disk 2717 is statically secured to an upper portion of the upper horizontal plate 2712, and the disk 2718 is statically secured to the bottom of the nut 2343.

[0389] An alternative aspiration system 2300" is illustrated in FIGS. 103-104. The aspiration system 2300" is similar in most aspects to the aspiration system 2300 of FIGS. 86-91, except that a static horizontal plate 2780 is rigidly coupled to the back wall 2708 or to any other static portion of the enclosure. The motor 2379 and the gearhead 2341 are attached to the bottom 2781 of the static horizontal plate 2780 and hang downwardly, not requiring, thus, any attachment to the base 2701 (FIG. 86). The stationary ball screw 2368, as in the aspiration system 2300, is coupled to a bi-directionally vertically-moveable slide 2709, via a horizontal pin 2710. There is a hole 2782 in the static horizontal plate 2780 configured to clear the ball screw 2368 and allow up-and-down freedom of movement of the ball screw 2368 in relation to the static horizontal plate 2780. The disk 2717 is rotationally coupled to and configured to rotate with the output shaft 2719. Horizontal plate 2712 is now configured to be moved up and down by the axial displacement between the disks 2717, 2718. The first toothed pulley 2722 is rotationally coupled or keyed to the output shaft 2719, but is configured to slide up and down in relation to the output shaft. In some embodiments, the output shaft 2719 has a hexagonal-shaped cross-section and there is a slightly larger hexagonal cavity (hole 2724) extending axially in the first toothed pulley 2722. As the horizontal plate 2712 carries both the first toothed pulley 2722 and the nut 2343, both of them are move up and down equally in unison with the horizontal plate 2712. The timing belt 2729 (or chain) is thus

not required to flex or translate (other than rotationally), because the first toothed pulley 2722 and the nut 2343 move up and down together.

[0390] Turning to FIG. 94, in a first time period A, the controller 2384 initiates operation of the high pressure pump 2312 at point A1 (e.g., t=0) to inject from the syringe 2366 through the second extension tube 2363 and the high pressure injection lumen 2310, but does not yet initiate operation of the peristaltic pump 2308. There is a noticeable pressure increase over this period. In some embodiments, first time period A is between about one second and about ten seconds, or between about one second and about five seconds, or about two or three seconds. At point A2, the controller 2384 then initiates operation of the peristaltic pump 2308. The controller 2384 can be programmed or enabled to determine point A2 based on a stored elapsed time after point A1. The controller can also be configured to recognize a proxy for internal pressure. The proxy in some embodiments comprises a measured current of the motor 2379, which increases with increased resistance, which can occur as the pressure inside the barrel 2373 increases. The proxy in other embodiments comprises a measured torque on the motor 2379 or on the output shaft 2719, for example via a torque sensor. Once a preset current or torque is achieved and is measured, the peristaltic pump 2308, for example, is turned on by the controller 2384. In alternative embodiments, the controller 2384 recognizes a measured injection pressure measured by a pressure sensor internal to the barrel 2373, and compares it to a pressure that is stored in memory as a target pressure. In some embodiments, the target pressure is between about 300 psi (20.4 atmospheres) and about 600 psi (40.8 atmospheres), or between about 375 psi (25.5 atmospheres) and about 525 psi (35.7 atmospheres). When the controller 2384 recognizes the target injection pressure (at A2), or other proxy, or simply the target elapsed time between A1 and A2, the controller 2384 then initiates operation of the peristaltic pump 2308. In other alternative embodiments, the controller 2384 initiates operation of the peristaltic pump 2308 after recognition of a measured target flow rate or a measured target flow velocity (e.g., with input from the output of a Doppler sensor). In some embodiments, the controller 2384 initiates operation of the peristaltic pump 2308 based on one or more of the following target injection parameters: target catheter input pressure, target minimum catheter input pressure, target maximum catheter input pressure, target mean catheter input pressure, target flow rate, motor current (e.g., motor 2397), motor speed (e.g., motor 2397), torque, target minimum flow rate, target maximum flow rate, target mean flow rate, target flow velocity, target minimum flow velocity, target maximum flow velocity, and target mean flow velocity.

[0391] With both the high pressure pump 2312 and the peristaltic pump 2308 operating simultaneously over second time period B, the measured injection pressure continues to increase until point B2, at which the mean injection pressure reaches the desired amount and the pulsatile injection provided by the flow oscillator 2420d may become more pronounced, as shown in third time period C. During the third time period C, the pulsatile cyclic or sinusoidal injection pressure (or flow rate, or flow velocity, etc.) can be visualized as valleys v. Pulsatility of injection may thus fully developed, but it is also possible that as aspiration from the peristaltic pump 2308 is added, there is additional time to fully develop the peak vacuum level. In some embodiments, a message to the user, or a light/LED, etc. indicates to the user when the injection pressure and the vacuum are both at desired levels. This curve can remain consistent, assuming

that there are no significant events such as blockage due to clogging (e.g., from trapped thrombus inside the catheter aspiration lumen 2304, or a catheter kink affecting the lumens 2304, 2310, etc.). The maintained pulsatility is aimed at maintaining a patent aspiration lumen 2304 that does not get clogged by aspirated portions of thrombus/clot. The jet from the orifice is configured to break up the thrombus into smaller pieces prior to the full aspiration. The initiation with the jet alone, during time period A, can serve to avoid a large initial piece of clot being sucked into the lumen and clogging it.

[0392] In alternative embodiments, instead of the first bump plate disk 2717 being configured to rotate in unison with the output shaft 2719, a relationship between the first bump plate disk 2717 and the output shaft 2719 can comprise coupling via planetary gears. Thus, the rotational speed of the output shaft 2719 can be greater or less than the rotational speed of the first bump plate disk 2717.

[0393] In some embodiments, the second bump plate disk 2718, instead of being configured to never rotate with respect to the upper horizontal plate 2712, can instead be configured to rotate with respect to the upper horizontal plate 2712, but only when a maximum torque is achieved. For example, a torque that is above a safety threshold. The second bump plate disk 2718 can be coupled to the upper horizontal plate 2712 by a bearing having a controlled amount of torque resistance that is configured to resist any torque below the upper safety threshold torque. Alternatively, a standard low-resistance bearing can be used, but a breakaway restraint can secure the bearing, such that it will break away at or above the upper safety threshold torque.

[0394] The flow oscillator 2420d of FIGS. 86-91 is configured for rotation in the first rotational direction 2735 during injection. After the procedure, or during a filling or refilling interval, the motor 2379 is operated (e.g., by the controller 2384) to cause the output shaft 2719 and nut 2343 to operate in an opposite rotational direction, that causes the ball screw 2368 to move downward, and the plunger 2389 to retract. This would be done, for example, to refill the interior of the barrel 2373 with saline. The shape of the first axial surface 2736 and the second axial surface 2737 are configured such that relative rotation and slipping between the two disks 2736, 2737 in the injection direction causes the pulsatile flow, as described; however, in the opposite relative direction, the slipping is controlled (due to the non-similar path) such that there is little or no pulsatile flow (e.g., as the barrel 2373 is filled). The plunger 2389 can also be loaded (pulled back) into the barrel 2373 in this manner, without significant pulsing.

[0395] FIGS. 92-93 illustrate a portion of an alternative flow oscillator 2420e comprising a first bump plate disk 2741 and a second bump plate disk 2742. The first bump plate disk 2741 and the second bump plate disk 2742 have axial surfaces 2743, 2744, respectively, that are not substantially similar to each other. The second surface 2744 comprises circumferentially-arrayed relatively flat valleys 2745 interspersed between substantially symmetric protrusions 2746. The first surface 2743 comprises a surface that is similar to the surface 2736 of the first disk 2717 in FIGS. 87-91. However, the maximum protrusion portion 2747 is radiused or filleted even more than the first axial surface 2736 and the second axial surface 2737 shown in FIGS. 87-91. The first disk 2741 is configured to be rotated in a first rotational direction 2748 in relation to the second disk 2742, and in a second, opposite rotational direction 2749 in relation to the second disk 2742. In some embodiments, as shown in FIGS. 92-93, there are the same number of

maximum protrusion portions 2747 on the first surface 2743 as there are valleys 2745 on the second surface 2744. In alternative embodiments, there are fewer maximum protrusion portions 2747 on the first surface 2743 than there are valleys 2745, on the second surface 2744. For example, in some embodiments, there are only three maximum protrusion portions 2747 on the first surface 2743 (e.g., separated by less than 180°, or located every) 120°, or six maximum protrusion portions 2747 (less than 90°, or located every) 60°, or between three and 36 maximum protrusion portions 2747, or between six and 24 maximum protrusion portions 2747, or between twelve and 36 maximum protrusion portions 2747.

[0396] Either by the relative rotation between disks 2717, 2718 or disks 2741, 2742, the return of the second disk 2718, 2742 axially back toward the first disk 2717, 2741 comprises a recoil or a slip. With this recoil the plunger 2389 in turn recoils, thus producing the valleys v. The total amount of axial height in the protrusions (in relation to the valleys), or the total axial variation in the surface contours can be controlled in fabricating the disks 2717, 2718, 2741, 2742, to produce a desired pressure variation or flow (rate, velocity, etc.) variation, such as that shown in third time period C in FIG. 94. In some embodiments, the total axial range (variation of the contour in the axial direction) is between about 0.2 mm and about 5 mm, or between about 0.3 mm and about 3 mm, or between about 0.3 mm and about 2 mm, or between about 0.3 mm and about 1 mm. By providing these predetermined dimensions on the disks 2717, 2718, 2741, 2742, a predetermined amount of axial movement is produced during operation.

[0397] A method for catheter-based aspiration includes providing a catheter having a distal portion configured for insertion within a blood vessel of a subject, the catheter including a first lumen having a distal opening at the distal portion of the catheter, a second lumen having a distal end at the distal portion of the catheter, and an orifice located at or near the distal end of the second lumen, the orifice configured to direct liquid into the first lumen at or near the distal opening of the first lumen, and further includes actuating an injector in a non-uniform manner to cause a pulsatile pressure of a liquid in the second lumen as the liquid is injected through the second lumen. In some embodiments, actuating the injector in a non-uniform manner includes repeatedly displacing a plunger in an interior of a barrel in a first direction along a longitudinal displacement axis by an increment, followed by movement of the barrel in a second direction, opposite the first direction. In some embodiments, movement of the barrel in the second direction corresponds to recoil of the injector following displacement thereof. In some embodiments, the recoil is a controlled recoil corresponding to a predetermined amount of movement in the second direction. In some embodiments, movement of the barrel in the second direction corresponds to controlled mechanical slip within an actuator. In some embodiments, repeatedly displacing the plunger includes displacing the plunger at a frequency of between 1 Hz and 8 Hz. In some embodiments, the method further includes reducing a pressure of the liquid in the second lumen to bring or maintain the pressure of the liquid below an injection pressure threshold. In some embodiments, reducing the pressure of the liquid in the second lumen includes actuating a valve in pressure communication with the second lumen. In some embodiments, the method further includes utilizing a mechanical oscillator coupled to the injector to at least partially cause the pulsatile pressure of the liquid, the mechanical oscillator including a first member and a second

member axially arrayed with respect to each other and configured such that changes in a relative rotational orientation between the first member and the second member cause reciprocal relative axial displacement between the first member and the second member, and wherein the first member is coupled to the plunger and configured to transfer motive force thereto along the longitudinal displacement axis. In some embodiments, the method further includes coupling a negative pressure source to a proximal portion of the first lumen of the catheter. In some embodiments, the negative pressure source includes a peristaltic pump. In some embodiments, the method further includes utilizing a controller to initiate operation of the injector prior to initiating operation of the peristaltic pump. In some embodiments, initiating operation of the injector prior to initiating operation of the peristaltic pump further includes initiating operation of the peristaltic pump only after the injector reaches a target injection parameter. In some embodiments, the target injection parameter includes one or more parameter selected from the list consisting of: a target catheter input pressure, a target minimum catheter input pressure, a target maximum catheter input pressure, a target mean catheter input pressure, a target flow rate, a target minimum flow rate, a target maximum flow rate, a target mean flow rate, a target flow velocity, a target minimum flow velocity, a target maximum flow velocity, and a target mean flow velocity.

[0398] FIGS. 96-97 illustrate an aspiration system 2900 that integrates together a high pressure pump 2902 (e.g., power injector), a peristaltic pump 2903, and control circuit board 2905, into a single enclosure 2901. The enclosure 2901 comprises a bottom plate 2906, a top plate 2907, a front plate 2908, a back plate 2909, a left plate 2910, and a right plate 2911. The enclosure 2901 is carried on a vertical pole 2912 that is coupled to a base 2913 having wheels 2914. In some embodiments, the pole height can be adjustable by a user (not shown). The pole 2912 is optional. In other embodiments, the enclosure 2901 can be configured to be placed on a table or stacked on other equipment. The peristaltic pump 2903 is a roller pump having a base 2915, a pressure shoe 2916 carried by the base 2915, and a rotatable head 2917, rotatably coupled to the base 2915, and carrying two or more rollers, as shown in FIG. 75 (rollers 2432a-d). The rollers are arrayed around a perimeter of the rotatable head 2917. The rotatable head 2917 is configured to be rotatable in at least a first rotational direction with respect to a rotational axis. The rotatable head 2917 is configured to be rotated by a motor 2918. The peristaltic pump 2903 is configured to connect to a power supply. As shown in FIG. 96, as assembled, the peristaltic pump 2903 is accessible to a user outside of the right plate 2911.

[0399] An aspiration catheter, such as the aspiration catheter 2402 of FIG. 75, is configured to be coupled to the peristaltic pump 2903 and to the high pressure pump 2902. The high pressure pump 2902 comprises a power injector having an electric motor 2919 outputting rotation to a gearhead 2920 (e.g., gearbox), which is configured to change a rotational speed (faster or slower) and/or to change a torque (lower or higher). The output of the gearhead 2920 is configured to indirectly drive a ball nut within a ball nut assembly 2921 over a stationary ball screw 2922 (e.g., via a belt drive configuration or chain drive configuration). The gearhead 2920 is mounted to a mounting plate 2942. The motor 2919 is configured to drive the ball nut in a clockwise direction and in a counter-clockwise direction. The ball screw 2922 is statically coupled to a plunger (similar to plunger 2389) that is sealingly carried within a barrel 2923

of a syringe 2924 and configured to be displaced along a longitudinal displacement path within the bore of the barrel 2923. The barrel 2923 of the syringe 2924 has a large bore, having a large internal volume, and the motor 2919 is configured to enable large torques to generate high injection pressures within the syringe 2924. The syringe 2924 includes a nozzle 2946 having an exit orifice 2947. The aspiration catheter 2402 is configured to be placed through a guiding catheter, an introducer sheath, or through direct blood vessel puncture. In some embodiments, the aspiration catheter 2402 can be a microcatheter. In other embodiments, the aspiration catheter 2402 can be configured to be utilized with a separate microcatheter and/or a guidewire. The pump 2902 is configured to connect to a power supply. A DC/DC power converter 2941 can provide the desired voltage to run different components, for example 24 Volts for the peristaltic pump 2903 and 48V for the high pressure pump 2902. The DC/DC power converter 2941 can be configured to protect against harsh, mobile use to stop or minimize over-temperature, overload, short-circuit, overvoltage and input under-voltage lock-out.

[0400] A syringe holder 2925 is coupled to a door 2926. Together, the syringe holder 2925 and the door 2926 are configured to slide in a path parallel to the left plate 2910 and the right plate 2911 that moves toward and away from the back plate 2909. A push button latch 2943 is coupled to the door 2926 to allow “push-to-open” and “push-to-lock” capability. In other embodiments, the door 2926 is configured to open in a pivoting manner, like a standard house front door. In other embodiments, the door 2926 is not required. The bottom end 2927 of the syringe 2924 is configured to couple to a circular opening 2928 in the syringe holder 2925. In use, after then bottom end 2927 of the syringe 2924 has been engaged with the opening 2928, the syringe holder 2925 and the door 2926 are slid into place (in a direction toward the back plate 2909). The barrel 2923 of the syringe 2924 now extends upwardly through a notch 2929 in the top plate 2907. The top plate 2907 includes an edge 2930 that acts as a stop against an upper edge 2931 of a flange 2932 of the syringe 2924. The syringe holder 2925 includes an edge 2933 that acts as a bottom stop against a lower edge 2934 of the syringe 2924. In other embodiments, the syringe 2924 comprises a lower male thread and the opening 2928 in the syringe holder 2925 comprises a female thread, wherein the male thread can be removably screwed into the female thread. An aligner 2945 aligns the base of the plunger to guide its movement through the barrel 2923 of the syringe 2924. If the syringe 2924 is loaded with the plunger (alone) sealingly inserted within the interior of the barrel 2923, the motor 2919 is then operated to drive the ball screw 2922 upward vertically to engage the ball screw 2922 or an end thereof into a proximal orifice in the plunger. If the syringe 2924 is loaded without the plunger, the motor 2919 is then operated to drive the ball screw 2922 upward vertically to engage the plunger into the interior of the barrel 2923.

[0401] The ball screw 2922 is pinned (as in FIGS. 86-88) to a carriage 2937 that is slidably coupled to an elongate guide rail 2938. The ball screw 2922 is thus configured to move upwardly and downwardly, as it is driven by the rotating ball nut, while the ball screw 2922 is maintained in a non-rotatable state. A main aspiration monitoring system (e.g., main aspiration monitoring system 2800 of FIGS. 86 and 95) comprising a pressure transducer (e.g., pressure transducer 2801) is configured such that its cable 2331 includes a RJ-45 compatible connector, configured to detachably connect to an RJ-45 jack 2935 which is accessible through a square hole 2936 in the front plate 2908. This

allows signals to be transmitted from the pressure transducer 2801 to the control circuit board 2905. A holding bracket 2944 is configured to hang a canister (e.g., canister 2358 of FIG. 86) used for the collection of aspirated thrombus or blood. The control circuit board 2905 is also configured to control a motor controller 2904 for the peristaltic pump 2903.

[0402] A display 2939 is carried on the front plate 2908 and is viewable to a user through a rectangular opening 2940 in the front plate 2908. The display 2939 is LCD, and includes resistive touch-screen control capability. Alternatively, other types of display can be utilized, and other types of touch-screen (e.g., capacitive). The aspiration system 2900 is compatible with the extension tubing 2338, 2363 of FIG. 86 and is configured to perform in a similar manner. As shown in FIG. 96, integrating the majority of the components into a single enclosure 2901, and carried on a mobile base 2913 via a pole 2912, allows rapid implementation into an emergent or a scheduled procedure, while using a small amount of space. It is also adaptable to a changing scenario during the procedure. For example, it is relatively easy to move the entire system 2900 from one side of a procedure table to the other, or to change rooms with the patient.

[0403] Any of the aspiration systems 1400, 1400', 1400", 400, 600, 2100, 2400, 2300, 2900 utilizing the peristaltic pump 1408, 408, 608, 2102/2108, 2408, 2308, 2903 or the centrifugal pump 1409 together with an aspiration catheter 1402, 1402', 402, 602, 2402, 2302 having both an aspiration lumen and an injection lumen can alternatively also be used with an aspiration catheter 202 having an aspiration lumen 204 and no injection lumen, or with an aspiration catheter 1402, 1402', 402, 602, 2402, 2302 without injecting through the injection lumen. The peristaltic pump 1408, 408, 608, 2102/2108, 2408, 2308, 2903 or the centrifugal pump 1409 alone can be used for the aspiration of thrombus. Any element configured to cause a particular pressure or injection pattern of the injectate can be considered a “drive unit.” Thus, a motor, or a solenoid, can be considered two different drive units. Additionally, if configured to work together, a motor and solenoid can be considered a single (compound) drive unit.

[0404] Using any of the aspiration systems described herein, a distal blood pressure can be measured in a diseased coronary artery, peripheral artery, or other artery by the open distal end of the aspiration lumen 1404 of the aspiration catheter 1402, with the pumps 1408, 1412 turned off or uncoupled, in order to determine a value for Fractional Flow Reserve (FFR), as disclosed in U.S. Pat. No. 6,565,514, Method and System for Determining Physiological Variables, to Svanerudh et al., which is incorporated herein by reference in its entirety for all purposes. The pressure sensor 1416 can be used to measure the pressure in the aspiration lumen 1404. For example, in a first step, the user assures that the pump 1412 is not actively pumping saline through the injection lumen 1410 and assures that the peristaltic pump 1408 is not actively aspirating through the aspiration lumen 1404. In a second step, the user places the open distal end 1405 of the aspiration lumen 1404 distal to an atherosclerotic lesion, stenosis, or partial blockage of interest in an artery, or a partial blockage or stenosis caused significantly by thrombus, or by a combination of atherosclerosis and thrombus. The user then in a third step measures a pressure at the open distal end 1405 of the aspiration lumen 1404 using the aspiration monitoring system 1414 while also measuring a pressure proximal to the lesion, for example, with a pressure transducer coupled to a guiding catheter. In a fourth step, the user obtains or calculates the Fractional

Flow Reserve (FFR), to help determine the significance of the stenosis of partial blockage.

[0405] In an alternative embodiment, the first disk comprises a first circumferentially-poled magnetic disk and the second disk comprises a second circumferentially-poled magnetic disk, such that relative rotational movement of the first disk with respect to the second disk at least partially serves to generate the reciprocal relative axial displacement, wherein the first disk and the second disk each comprise paired poling configurations, such that when same poles are overlayed, the first disk and the second disk are axially moved apart by one or more repulsive force, and when opposite poles are overlayed, the first disk and the second disk are axially moved closer to each other by one or more attractive force. In some embodiments, the system further comprise(s) a non-magnetic buffer layer between the first disk and the second disk, the buffer layer configured to minimize direct frictional contact between the first disk and the second disk.

[0406] FIGS. 100-101 illustrate a surgical aspiration probe 2950 configured to be used with any of the aspiration systems 1400, 1400', 1400", 400, 600, 2100, 2400, 2300, 2900 disclosed herein. Instead of a catheter shaft, the surgical aspiration probe 2950 comprises a handle 2951 and a hypodermic tubular shaft 2952. The shaft 2952 comprises stainless steel. In other embodiments, the shaft 2952 comprises other relatively stiff biocompatible metals or polymers. As shown in FIG. 102, the shaft 2952 is configured to be placed through an introducer sheath 2953 that has been inserted into a burr hole 2954 in the cranium 2955 of a patient 2956. The shaft 2952 is also configured to be inserted through an endoscope. In some cases, the endoscope is inserted through the burr hole, and the shaft 2952 is inserted through the endoscope lumen.

[0407] The handle 2951 comprises a first half 2957 and a second half 2958, which are connected to each other with screws 2959a-d, closing the halves 2957, 2958 over the shaft 2952. The screws 2959a-d are placed through holes 2960 in the second half 2958 and threadingly engage with female threaded holes 2961 in the first half 2957 to secure the first half 2957 and the second half 2958 together. In alternative embodiments, instead of using screws 2959a-d, the first half 2957 and the second half 2958 are bonded (adhesive, epoxy, hot melt) or welded (ultrasonically) together. A high pressure injection tube 2962 is inserted into an aspiration lumen 2963 of the shaft 2952 and is bonded to the inside wall of the aspiration lumen 2963 with an adhesive or epoxy. At a distal end of the shaft 2952, continuously along the length of the shaft 2952, or at several different locations along shaft 2952. The high pressure injection tube 2962 can comprise polyimide, and comprises a lumen 2964 extending therethrough. The lumen 2964 is blocked at a distal end 2965 of the injection tube 2962 by a blocking material 2966, which can comprise an epoxy, an adhesive, a hot melt, and/or a friction plug. Immediately proximal to the blocking material 2966, is an orifice 2967 in the wall 2968 of the injection tube 2962. Thus, high pressure liquid, such as saline, can be injected from a proximal end 2969 of the lumen 2964, such that it travels down the lumen 2964 and exits out the orifice 2967, into the aspiration lumen 2963 of the shaft 2952.

[0408] Thus, a negative pressure is created to force material that is external and adjacent the open distal end 2970 into the aspiration lumen 2963. The tip configuration of any of the aspiration catheters of any of the aspiration systems 1400, 1400', 1400", 400, 600, 2100, 2400, 2300, 2900 of this disclosure can be utilized to tailor the desired effect. A peristaltic pump 1408, 408, 608, 2102/2108, 2408, 2308,

2903 or the centrifugal pump 1409 can be additionally used to provide a negative pressure at a proximal end 2971 of the aspiration lumen 2963. A y-connector 2972 comprises a first luer 2973 that is hydraulically coupled to the lumen 2964 of the injection tube 2962, and a second luer 2974 that is hydraulically coupled to the aspiration lumen 2963. Each of the halves 2957, 2958 of the handle 2951 includes a proximal semi-circular hole 2975, 2976 configured to be closed around the first luer 2973 and an angle side semi-circular hole 2977, 2978 configured to be closed around the second luer 2974, as shown in FIG. 100. A hole 2979 on the top 2980 of the first half 2957 is configured to contain a push button 2981, which comprises a push button element 2982, a base 2983, and a dome seal 2984. Two screws 2985a-b insert through holes in the base 2983 to secure the push button element 2982 in place within the first half 2957, and seal the dome seal 2984 against an underside of the first half 2957, surrounding the hole 2979.

[0409] A pressure transducer 2986 is coupled to the distal end of the y-connector 2972, which is hydraulically coupled to the aspiration lumen 2963, to measure a pressure (e.g., negative pressure) therein. A signal from the pressure transducer 2986 is carried by insulated conductors 2987 which pass through two semi-circular holes 2988, 2989 in the halves 2957, 2958, which close around the insulated conductors 2987. Alternatively, the signal can be transmitted wirelessly. In addition, a signal from the push button element 2982 is carried by insulated conductors 2990, which also pass through the holes 2988, 2989. The signals from the push button element 2982, carried by the conductors 2990, can be configured to communicate with a controller of any of the aspiration systems 1400, 1400', 1400", 400, 600, 2100, 2400, 2300, 2900. For example, the push button 2981 can be utilized by a user to turn the system on or off. Pressing the push button 2981 to turn the system on can initiate the controller such that the controller first begins the injection through the lumen 2964 of the injection tube 2962, and then begins the aspiration through the aspiration lumen 2963.

[0410] Turning to FIG. 102, a burr hole 2954 is made in the cranium 2955 of a patient 2956. A peel away sheath 2953 (or a standard non-peel-away sheath) is placed through the burr hole 2954 and inserted until its distal end 2991 is located at a desired position 2994 in or adjacent a hemorrhage 2992 (or tumor, or other undesirable element) within the brain 2993 of the patient 2956. The hemorrhage 2992 may have been the result of a ruptured artery that has bled into the brain 2993. Again, the shaft 2952 is also configured to be inserted through an endoscope. The distal end 2995 of the shaft 2952 is moved out from a distal opening 2996 of the sheath 2953, and moved back, to aspirate the contents of the hemorrhage 2992 (and/or other material) at different locations, and to more completely aspiration the hemorrhage 2992. When the aspiration is complete, the sheath 2953 can be split in half (peeled away) and removed, the shaft 2952 can be retracted from the burr hole 2954, and the burr hold 2954 can be closed up with bone wax. In some cases, a craniotomy is used, to expose a larger amount of area, for example, in the case of a large hemorrhage 2992. In addition to or instead of removal of hemorrhage 2992, the surgical aspiration probe 2950 can be utilized to remove clot/thrombus from the brain.

[0411] FIGS. 105A-108 illustrate an alternative high-pressure pump 3002 for the aspiration system 2900 of FIGS. 96-97. The high-pressure pump 3002 comprises a power injector having an electric motor 3019 outputting rotation to a gearhead 3020 (e.g., gearbox), which is configured to

change a rotational speed (faster or slower) and/or to change a torque (lower or higher). The motor 3019 is connected to a power supply and controller (not shown) via cables 3025 and one or more connectors 3026. The output of the gearhead 3020 is configured to indirectly drive a ball nut 3098 within a ball nut assembly 3021 over a stationary (non-rotational) ball screw 3022 via chain 3099 (or alternatively, a belt). The gearhead 3020 is mounted to a mounting plate 3042 via screws 3038. The motor 3019 is configured to drive the ball nut 3098 in a clockwise direction and in a counter-clockwise direction. The ball screw 3022 is statically coupled to a plunger (similar to plunger 2389) that is sealingly carried within a barrel 2923 of a syringe 2924 and configured to be displaced along a longitudinal displacement path within the bore of the barrel 2923 (FIG. 97). The pump 3002 is configured to connect to a power supply.

[0412] A housing 3023 is attached to the mounting plate 3042 by several screws 3024. Alternatively, the housing 3023 can be coupled to the mounting plate 3042 by welding, brazing, adhesive, epoxy, hot melt, or other joining materials and methods. Turning to FIGS. 106-108, an output shaft 3027 from the gearhead 3020 is coupled to a drive sprocket 3028. The drive sprocket 3028 is rotatably held within a circular cavity 3029 of the housing 3023 by a ball bearing 3030. The drive sprocket 3028 turns within the same longitudinal axis LA1 as the output shaft 3027. A driven sprocket 3031 is rotatably coupled to the ball nut 3098 and both turn within the same longitudinal axis LA2 as each other. A continuous 360° extending chain 3099 is configured to engage with teeth 3032, 3033 of the sprockets 3028, 3031, so that the drive sprocket 3028 is able to drive the driven sprocket 3031. In some embodiments, the drive sprocket 3028 and the driven sprocket 3031 have the same number of teeth as each other. In some embodiments, the drive sprocket 3028 and the driven sprocket 3031 have the diameter as each other. In the embodiment of FIGS. 105A-108, the drive sprocket 3028 has a smaller diameter than the driven sprocket 3031 and has fewer teeth, and thus is configured to drive the driven sprocket 3031 (and thus the ball nut 3098) at a slower rotational speed, but with an increased torque. The gear ratio of the drive sprocket 3028 and driven sprocket 3031 can in some embodiments be between 1.5 to 2.5.

[0413] The ball nut 3098 drives the ball screw 3022 in a longitudinal direction, and the ball screw 3022 passes through a sleeve bearing 3034 which maintains its straight movement, without adding large amounts of frictional resistance. The sleeve bearing 3034 can comprise a lubricious material or can be a lubricated component. A flow oscillator 3035 causes back-and-forth axial oscillation (e.g., up-and-down motion) via two circular bump plates or “ripple plates” 3036, 3037 (disks) as their relative rotational orientation is changed with respect to each other, also by the driving of the motor 3019/gearhead 3020/output shaft 3027. Thus, as the drive sprocket 3028 is turned about longitudinal axis LA1, it generally maintains its longitudinal position. Whereas, when the ball nut 3098 is turned about the longitudinal axis LA2, it is caused to move back and forth longitudinally, due to the axial displacement caused by the ripple plate 3036 and ripple plate 3037 rotationally slipping against each other. In some embodiments, wherein the driven sprocket 3031 and the ball nut 3098 are rigidly coupled together, the chain 3099 is able to slightly flex or curve in order to allow the driven sprocket 3031 to move axially (in both directions) along with the ball nut 3098. In other embodiments, the driven sprocket 3031 and the ball nut 3098 are keyed together to allow for some axial slippage between the two, but to maintain one-to-one rotation. For example, the ball nut 3098

can comprise an external square, hex or other non-circular shape extending on the side toward the driven sprocket 3031 such that it freely passes through a similarly-shaped but slightly larger hole in the driven sprocket 3031. Thus, as the ball nut 3098 moves back-and-forth axially, the driven sprocket 3031 generally maintains its longitudinal position, and the chain 3099 does not need to flex or curve. A second sleeve bearing 3039 (see FIG. 107), comprising a lubricious or lubricated material, surrounds the ripple plates 3036, 3037 to help stabilize their rotation and orientation, without adding large amounts of frictional resistance.

[0414] In alternative embodiments, any of the embodiments presented herein utilizing a ball screw 2368, 2922, 3022 can instead utilize a screw that is turned by the motor/gearhead/output shaft, configured to threadingly engage with a non-rotating nut coupled to the housing. The distal end of the screw can be coupled to the plunger with a rotatable connection (rotational coupling). Thus, the screw longitudinally displaces and rotates while the plunger longitudinally displaces with the screw, but does not rotate.

[0415] The following clauses include examples of apparatus of the disclosure:

[0416] Clause 1: In one example, a system for catheter-based aspiration includes an aspiration catheter having an aspiration lumen and an injection lumen, the injection lumen having a distal orifice configured for directing liquid into a distal portion of the aspiration lumen, and an injector configured to pressurize the liquid in an oscillating manner within the injection lumen, such that liquid exits the distal orifice and enters the distal portion of the aspiration lumen with a variable flow rate and/or variable flow velocity, wherein the injector includes a barrel having an interior, a plunger configured to sealingly change an effective volume of the interior of the barrel, and a controller configured to control movement of the plunger within the interior of the barrel.

[0417] Clause 2: In some examples, the system of clause 1 further includes wherein the controller is configured to operate a drive unit, the drive unit configured to change the relationship between the plunger and the barrel.

[0418] Clause 3: In some examples, the system of clause 2 further includes wherein the drive unit includes a screw.

[0419] Clause 4: In some examples, the system of clause 3 further includes wherein the drive unit is configured to turn the screw in a clockwise direction and to turn the screw in a counter-clockwise direction.

[0420] Clause 5: In some examples, the system of any one of clauses 2-4 further includes wherein the drive unit includes a motor.

[0421] Clause 6: In some examples, the system of clause 5 further includes wherein the controller is configured to operate the motor at a first motor speed at an initiation of a first injection cycle and to adjust to a second motor speed at a time within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed.

[0422] Clause 7: In some examples, the system of clause 6 further includes wherein the first motor speed is between 1.5 times and 3.5 times greater than the second motor speed.

[0423] Clause 8: In some examples, the system of clause 6 further includes wherein the first motor speed is between 2 times and 3 times greater than the second motor speed.

[0424] Clause 9: In some examples, the system of either one of clauses 7-8 further includes wherein the second motor speed is configured to be the main motor speed throughout the first injection cycle.

[0425] Clause 10: In some examples, the system of any one of claims 1-5 further includes wherein the injector includes a relief valve.

[0426] Clause 11: In some examples, the system of clause 10 further includes wherein the relief valve is configured to mechanically establish a maximum injection pressure.

[0427] Clause 12: In some examples, the system of any one of clauses 1-11 further includes a peristaltic pump configured for driving fluid from the distal portion of the aspiration lumen to a proximal portion of the aspiration lumen.

[0428] Clause 13: In some examples, the system of clause 12 further includes a compressible tube configured to be hydraulically coupled to the aspiration lumen and configured to be engaged with the peristaltic pump.

[0429] Clause 14: In some examples, the system of any one of clauses 1-13 further includes a switch configured to change the effect of the injection of fluid by the injector from the oscillating manner to a non-oscillating manner.

[0430] Clause 15: In some examples, the system of any one of clauses 1-13 further includes a switch configured to change the effect of the injection of fluid by the injector from the oscillating manner to a damped oscillating manner.

[0431] Clause 16: In some examples, the system of any one of clauses 5-9 further includes a transducer configured to monitor electrical current of the motor.

[0432] Clause 17: In some examples, the system of clause 16 further includes wherein the controller is configured to calculate an injection pressure of the injector based at least in part on the measured electrical current.

[0433] Clause 18: In some examples, the system of any one of clauses 1-17 further includes wherein the oscillating manner includes a 3-8 Hz oscillation.

[0434] Clause 19: In some examples, the system of any one of clauses 1-17 further includes wherein the oscillating manner includes a 4-7 Hz oscillation.

[0435] Clause 20: In some examples, the system of any one of clauses 1-17 further includes wherein the oscillating manner includes a 5-6 Hz oscillation.

[0436] Clause 21: In another example, a system for catheter-based aspiration includes an aspiration catheter having an aspiration lumen and an injection lumen, the injection lumen having a distal orifice configured for directing liquid into a distal portion of the aspiration lumen, and an injector configured to pressurize the liquid in an oscillating manner within a range of between about 200 psi and about 1500 psi at a proximal portion of the injection lumen, such that liquid exits the distal orifice and enters the distal portion of the aspiration lumen with a variable flow rate and/or variable flow velocity.

[0437] Clause 22: In some examples, the system of clause 21 further includes wherein the injector is configured to pressurize the liquid in an oscillating manner between about 600 psi and about 700 psi at the proximal portion of the injection lumen.

[0438] Clause 23: In some examples, the system of clause 21 further includes wherein the injector is configured to pressurize the liquid such that the flow rate varies between values that include 31 ml/min.

[0439] Clause 24: In some examples, the system of clause 21 further includes wherein the injector is configured to pressurize the liquid such that the flow rate varies between about 20 ml/min and about 45 ml/min.

[0440] Clause 25: In some examples, the system of any one of clauses 21-24 further includes wherein injector includes a drive unit configured to power the injection and a controller configured to control the drive unit.

[0441] Clause 26: In some examples, the system of clause 25 further includes wherein the drive unit includes a solenoid.

[0442] Clause 27: In some examples, the system of clause 26 further includes wherein the drive unit further includes a valve coupled to the solenoid.

[0443] Clause 28: In some examples, the system of clause 27 further includes wherein the drive unit includes a motor.

[0444] Clause 29: In some examples, the system of any one of clauses 21-25 further includes a compressible tube configured to be hydraulically coupled to the injection lumen, wherein oscillatory changes in the internal cross-sectional space at a first location of the compressible tube at least partially promotes the oscillating manner.

[0445] Clause 30: In some examples, the system of clause 29 further includes a variable pincher configured to engage an external portion of the compressible tube at the first location and to variably change the internal cross-sectional space by variable external compression.

[0446] Clause 31: In some examples, the system of clause 30 further includes wherein the variable external compression is sinusoidal.

[0447] Clause 32: In some examples, the system of any one of clauses 21-31 further includes a peristaltic pump configured for driving fluid from the distal portion of the aspiration lumen to a proximal portion of the aspiration lumen.

[0448] Clause 33: In some examples, the system of clause 32 further includes an additional compressible tube configured to be hydraulically coupled to the aspiration lumen and configured to be engaged with the peristaltic pump.

[0449] Clause 34: In some examples, the system of any one of clauses 21-33 further includes wherein the oscillating manner includes a 3-8 Hz oscillation.

[0450] Clause 35: In some examples, the system of any one of clauses 21-33 further includes wherein the oscillating manner includes a 4-7 Hz oscillation.

[0451] Clause 36: In some examples, the system of any one of clauses 21-33 further includes wherein the oscillating manner includes a 5-6 Hz oscillation.

[0452] Clause 37: In yet another example, a system for catheter-based aspiration includes an injection tube including an injection lumen having a distal orifice, and an injector configured to pressurize the liquid in an oscillating manner within the injection lumen, such that liquid exits the distal orifice with a variable flow rate and/or variable flow velocity, wherein the injector includes a barrel having an interior, a plunger configured to sealingly change an effective volume of the interior of the barrel, and a controller configured to control movement of the plunger within the interior of the barrel.

[0453] Clause 38: In some examples, the system of clause 37 further includes wherein the controller is configured to operate a drive unit, the drive unit configured to change the relationship between the plunger and the barrel.

[0454] Clause 39: In some examples, the system of clause 38 further includes wherein the drive unit includes a screw.

[0455] Clause 40: In some examples, the system of clause 39 further includes wherein the drive unit is configured to turn the screw in a clockwise direction and to turn the screw in a counter-clockwise direction.

[0456] Clause 41: In some examples, the system of any one of clauses 38-40 further includes wherein the drive unit includes a motor.

[0457] Clause 42: In some examples, the system of clause 41 further includes wherein the controller is configured to operate the motor at a first motor speed at an initiation of a

first injection cycle and to adjust to a second motor speed at a time within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed.

[0458] Clause 43: In some examples, the system of clause 42 further includes wherein the first motor speed is between 1.5 times and 3.5 times greater than the second motor speed.

[0459] Clause 44: In some examples, the system of clause 42 further includes wherein the first motor speed is between 2 times and 3 times greater than the second motor speed.

[0460] Clause 45: In some examples, the system of any one of clauses 43-44 further includes wherein the second motor speed is configured to be the main motor speed throughout the first injection cycle.

[0461] Clause 46: In some examples, the system of any one of clauses 37-41 further includes wherein the injector includes a relief valve.

[0462] Clause 47: In some examples, the system of clause 46 further includes wherein the relief valve is configured to mechanically establish a maximum injection pressure.

[0463] Clause 48: In some examples, the system of any one of clauses 37-47 further includes a switch configured to change the effect of the injection of fluid by the injector from the oscillating manner to a non-oscillating manner.

[0464] Clause 49: In some examples, the system of any one of clauses 37-47 further includes a switch configured to change the effect of the injection of fluid by the injector from the oscillating manner to a damped oscillating manner.

[0465] Clause 50: In some examples, the system of any one of clauses 41-45 further includes a transducer configured to monitor electrical current of the motor.

[0466] Clause 51: In some examples, the system of clause 50 further includes wherein the controller is configured to calculate an injection pressure of the injector based at least in part on the measured electrical current.

[0467] Clause 52: In some examples, the system of any one of clauses 37-51 further includes wherein the oscillating manner includes a 3-8 Hz oscillation.

[0468] Clause 53: In some examples, the system of any one of clauses 37-51 further includes wherein the oscillating manner includes a 4-7 Hz oscillation.

[0469] Clause 54: In some examples, the system of any one of clauses 37-51 further includes wherein the oscillating manner includes a 5-6 Hz oscillation.

[0470] Clause 55: In still another example, a system for catheter-based aspiration includes an aspiration catheter having an aspiration lumen and an injection lumen, the injection lumen having an orifice located at or near a distal end thereof, the orifice configured for directing liquid into a distal portion of the aspiration lumen, an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the distal portion of the aspiration lumen, and a flow oscillator configured to cause a variable flow rate and/or variable flow velocity of the liquid that enters the distal portion of the aspiration lumen.

[0471] Clause 56: In some examples, the system of clause 55 further includes wherein the flow oscillator includes a relief valve.

[0472] Clause 57: In some examples, the system of clause 56 further includes wherein the relief valve is configured to mechanically establish a maximum injection pressure.

[0473] Clause 58: In some examples, the system of clause 55 further includes a controller configured to operate the flow oscillator.

[0474] Clause 59: In some examples, the system of any one of clauses 55 or 58 further includes wherein the flow oscillator includes a drive unit.

[0475] Clause 60: In some examples, the system of clause 59 further includes wherein the drive unit includes a screw.

[0476] Clause 61: In some examples, the system of clause 60 further includes wherein the drive unit is configured to turn the screw in a clockwise direction and to turn the screw in a counter-clockwise direction.

[0477] Clause 62: In some examples, the system of any one of clauses 59-61 further includes wherein the drive unit includes a motor.

[0478] Clause 63: In some examples, the system of clause 58 further includes wherein the flow oscillator includes a drive unit including a motor, and wherein the controller is configured to operate the motor at a first motor speed at an initiation of a first injection cycle and to adjust to a second motor speed at a time within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed.

[0479] Clause 64: In some examples, the system of clause 63 further includes wherein the first motor speed is between 1.5 times and 3.5 times greater than the second motor speed.

[0480] Clause 65: In some examples, the system of clause 63 further includes wherein the first motor speed is between 2 times and 3 times greater than the second motor speed.

[0481] Clause 66: In some examples, the system of any one of clauses 64-65 further includes wherein the second motor speed is configured to be the main motor speed throughout the first injection cycle.

[0482] Clause 67: In some examples, the system of any one of clauses 55-66 further includes a peristaltic pump configured for driving fluid from the distal portion of the aspiration lumen to a proximal portion of the aspiration lumen.

[0483] Clause 68: In some examples, the system of clause 67 further includes a compressible tube configured to be hydraulically coupled to the aspiration lumen and configured to be engaged with the peristaltic pump.

[0484] Clause 69: In some examples, the system of any one of clauses 55-68 further includes a switch configured to change the effect of the flow oscillator from an oscillating manner to a non-oscillating manner.

[0485] Clause 70: In some examples, the system of any one of clauses 55-68 further includes a switch configured to change the effect of the flow oscillator from an oscillating manner to a damped oscillating manner.

[0486] Clause 71: In some examples, the system of any one of clauses 55-68 further includes a switch configured to change the effect of the flow oscillator from a variable manner to a non-variable manner.

[0487] Clause 72: In some examples, the system of any one of clauses 63-66 further includes a transducer configured to monitor electrical current of the motor.

[0488] Clause 73: In some examples, the system of clause 72 further includes wherein the controller is configured to calculate an injection pressure of the injector based at least in part on the measured electrical current.

[0489] Clause 74: In some examples, the system of any one of clauses 55-73 further includes wherein the variable flow rate and/or variable flow velocity includes a 3-8 Hz oscillation.

[0490] Clause 75: In some examples, the system of any one of clauses 55-73 further includes wherein the variable flow rate and/or variable flow velocity includes a 4-7 Hz oscillation.

[0491] Clause 76: In some examples, the system of any one of clauses 55-73 further includes wherein the variable flow rate and/or variable flow velocity includes a 5-6 Hz oscillation.

[0492] Clause 77: In still another example, a system for catheter-based aspiration includes an aspiration catheter having an aspiration lumen and an injection lumen, the injection lumen having an orifice located at or near a distal end thereof, the orifice configured for directing liquid into a distal portion of the aspiration lumen, an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the distal portion of the aspiration lumen, and a flow oscillator configured to cause an oscillating pressure of the liquid that within the injection lumen.

[0493] Clause 78: In some examples, the system of clause 77 further includes wherein the flow oscillator includes a relief valve.

[0494] Clause 79: In some examples, the system of clause 78 further includes wherein the relief valve is configured to mechanically establish a maximum injection pressure.

[0495] Clause 80: In some examples, the system of clause 77 further includes a controller configured to operate the flow oscillator.

[0496] Clause 81: In some examples, the system of either one of clauses 77 or 80 further includes wherein the flow oscillator includes a drive unit.

[0497] Clause 82: In some examples, the system of clause 81 further includes wherein the drive unit includes a screw.

[0498] Clause 83: In some examples, the system of clause 82 further includes wherein the drive unit is configured to turn the screw in a clockwise direction and to turn the screw in a counter-clockwise direction.

[0499] Clause 84: In some examples, the system of any one of clauses 81-83 further includes wherein the drive unit includes a motor.

[0500] Clause 85: In some examples, the system of clause 80 further includes wherein the flow oscillator includes a drive unit including a motor, and wherein the controller is configured to operate the motor at a first motor speed at an initiation of a first injection cycle and to adjust to a second motor speed at a time within five seconds to two minutes from the initiation of the first injection cycle, the second motor speed lower than the first motor speed.

[0501] Clause 86: In some examples, the system of clause 85 further includes wherein the first motor speed is between 1.5 times and 3.5 times greater than the second motor speed.

[0502] Clause 87: In some examples, the system of clause 85 further includes wherein the first motor speed is between 2 times and 3 times greater than the second motor speed.

[0503] Clause 88: In some examples, the system of any one of clauses 86-87 further includes wherein the second motor speed is configured to be the main motor speed throughout the first injection cycle.

[0504] Clause 89: In some examples, the system of any one of clauses 77-88 further includes a peristaltic pump configured for driving fluid from the distal portion of the aspiration lumen to a proximal portion of the aspiration lumen.

[0505] Clause 90: In some examples, the system of clause 89 further includes a compressible tube configured to be hydraulically coupled to the aspiration lumen and configured to be engaged with the peristaltic pump.

[0506] Clause 91: In some examples, the system of any one of clauses 77-90 further includes a switch configured to change the effect of the flow oscillator from an oscillating manner to a non-oscillating manner.

[0507] Clause 92: In some examples, the system of any one of clauses 77-90 further includes a switch configured to change the effect of the flow oscillator from an oscillating manner to a damped oscillating manner a switch configured

to change the effect of the flow oscillator from an oscillating manner to a damped oscillating manner.

[0508] Clause 93: In some examples, the system of any one of clauses 77-90 further includes a switch configured to change the effect of the flow oscillator from a variable manner to a non-variable manner.

[0509] Clause 94: In some examples, the system of any one of clauses 85-88 further includes a transducer configured to monitor electrical current of the motor.

[0510] Clause 95: In some examples, the system of clause 94 further includes wherein the controller is configured to calculate an injection pressure of the injector based at least in part on the measured electrical current.

[0511] Clause 96: In some examples, the system of any one of clauses 77-95 further includes wherein variable pressure includes a pressure oscillation within the range of 200 pounds per square inch to 1500 pounds per square inch.

[0512] Clause 97: In some examples, the system of any one of clauses 1-11, 21-31, or 77-88 further includes a negative pressure source.

[0513] Clause 98: In some examples, the system of clause 97 further includes wherein the negative pressure source includes a variable negative pressure source.

[0514] Clause 99: In some examples, the system of clause 98 further includes wherein the variable negative pressure source is configured to deliver a variable negative pressure at a frequency of between 3 Hz and 8 Hz.

[0515] Clause 100: In still another example, a system for catheter-based aspiration includes an aspiration catheter having a distal portion configured for insertion within a blood vessel of a subject, the aspiration catheter including an aspiration lumen having a distal opening at the distal portion of the aspiration catheter, an injection lumen having a distal end at the distal portion of the aspiration catheter, and an orifice located at or near the distal end of the injection lumen, the orifice configured to direct liquid into the aspiration lumen at or near the distal opening of the aspiration lumen, the system further including an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the aspiration lumen, and a mechanical oscillator coupled to the injector and configured to cause a pulsatile pressure of the liquid as it is injected through the injection lumen, wherein the injector includes a barrel and a plunger, the plunger sealingly displaceable within an interior of the barrel along a longitudinal displacement axis, wherein the mechanical oscillator includes a first disk and a second disk axially arrayed with respect to each other and configured such that changes based upon relative rotational orientation between the first disk and the second disk cause reciprocal relative axial displacement between the first disk and the second disk, and wherein the first disk is coupled to the plunger and configured to transfer motive force thereto along the longitudinal displacement axis, wherein a first one of the first disk or second disk includes a first side, and the other of the first disk or second disk includes a second side, the first side facing the second side, the first side having series of circumferentially-arrayed axial dimensional variations, and the second side including a first protrusion that extends less than 180° on the second side, the first protrusion configured to physically engage with the first side such that relative rotational movement of the first protrusion with respect to the series of circumferentially-arrayed axial dimensional variations at least partially generates the reciprocal relative axial displacement, and wherein the circumferentially-arrayed axial dimensional variations include a series of radially-extending projections, and wherein the circumferentially-arrayed axial dimensional

variations further include a series of radially-extending depressions, interspersed between the radially-extending projections.

[0516] Clause 101: In some examples, the system of clause 100 further includes wherein a first one of the first disk or second disk includes a ceramic, and the other of the first disk or second disk includes a metal.

[0517] Clause 102: In some examples, the system of clause 100 further includes a screw configured to drive the plunger.

[0518] Clause 103: In some examples, the system of clause 102 further includes a chain coupled between the first disk and the screw.

[0519] Clause 104: In some examples, the system of clause 102 further includes a belt coupled between the first disk and the screw.

[0520] Clause 105: In still another example, a system for catheter-based aspiration includes an aspiration catheter having a distal portion configured for insertion within a blood vessel of a subject, the aspiration catheter including an aspiration lumen having a distal opening at the distal portion of the aspiration catheter, an injection lumen having a distal end at the distal portion of the aspiration catheter, and an orifice located at or near the distal end of the injection lumen, the orifice configured to direct liquid into the aspiration lumen at or near the distal opening of the aspiration lumen, the system further including an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the aspiration lumen, a mechanical oscillator coupled to the injector and configured to cause a pulsatile pressure of the liquid as it is injected through the injection lumen, and a controller configured to control pulsatility of the liquid.

[0521] Clause 106: In some examples, the system of clause 105 further includes wherein the controller is configured to operate the mechanical oscillator and injector at an injection oscillation frequency of between about 1 Hz and about 8 Hz.

[0522] Clause 107: In yet another example, a system for catheter-based aspiration includes an aspiration catheter having a distal portion configured for insertion within a blood vessel of a subject, the aspiration catheter including an aspiration lumen having a distal opening at the distal portion of the aspiration catheter, an injection lumen having a distal end at the distal portion of the aspiration catheter, and an orifice located at or near the distal end of the injection lumen, the orifice configured to direct liquid into the aspiration lumen at or near the distal opening of the aspiration lumen, the system further including an injector configured to pressurize the liquid within the injection lumen, such that liquid exits the orifice and enters the aspiration lumen, a mechanical oscillator coupled to the injector and configured to cause a pulsatile pressure of the liquid as it is injected through the injection lumen, and a negative pressure source configured to couple to a proximal portion of the aspiration lumen of the aspiration catheter.

[0523] Clause 108: In some examples, the system of clause 107 further includes wherein the negative pressure source includes a peristaltic pump.

[0524] While the foregoing is directed to embodiments of the present disclosure, other and further embodiments may be devised without departing from the basic scope thereof.

[0525] The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about",

and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

[0526] For purposes of the present disclosure and appended claims, the conjunction "or" is to be construed inclusively (e.g., "an apple or an orange" would be interpreted as "an apple, or an orange, or both"; e.g., "an apple, an orange, or an avocado" would be interpreted as "an apple, or an orange, or an avocado, or any two, or all three"), unless: (i) it is explicitly stated otherwise, e.g., by use of "either . . . or," "only one of," or similar language; or (ii) two or more of the listed alternatives are mutually exclusive within the particular context, in which case "or" would encompass only those combinations involving non-mutually-exclusive alternatives. For purposes of the present disclosure and appended claims, the words "comprising," "including," "having," and variants thereof, wherever they appear, shall be construed as open-ended terminology, with the same meaning as if the phrase "at least" were appended after each instance thereof.

1-15. (canceled)

16. (canceled)

17. A method for catheter-based aspiration, comprising: providing a catheter having a distal portion configured for insertion within a blood vessel of a subject, the catheter comprising:  
a first lumen having a distal opening at the distal portion of the catheter;  
a second lumen having a distal end at the distal portion of the catheter; and  
an orifice located at or near the distal end of the second lumen, the orifice configured to direct liquid into the first lumen at or near the distal opening of the first lumen; and

actuating an injector in a non-uniform manner to cause a pulsatile pressure of a liquid in the second lumen as the liquid is injected through the second lumen, wherein actuating the injector in a non-uniform manner comprises repeatedly displacing a plunger in an interior of a barrel in a first direction along a longitudinal displacement axis by an increment, followed by movement of the barrel in a second direction, opposite the first direction.

18. The method of claim 17, wherein movement of the barrel in the second direction corresponds to recoil of the injector following displacement thereof.

19. The method of claim 18, wherein the recoil is a controlled recoil corresponding to a predetermined amount of movement in the second direction.

20. The method of claim 17, wherein movement of the barrel in the second direction corresponds to controlled mechanical slip within an actuator.

21. The method of claim 17, wherein repeatedly displacing the plunger comprises displacing the plunger at a frequency of between 1 Hz and 8 Hz.

22. The method of claim 17, further comprising reducing a pressure of the liquid in the second lumen to bring or maintain the pressure of the liquid below an injection pressure threshold.

23. The method of claim 22, wherein reducing the pressure of the liquid in the second lumen comprises actuating a valve in pressure communication with the second lumen.

**24.** The method of claim 17, further comprising utilizing a mechanical oscillator coupled to the injector to at least partially cause the pulsatile pressure of the liquid, the mechanical oscillator comprising a first member and a second member axially arrayed with respect to each other and configured such that changes in a relative rotational orientation between the first member and the second member cause reciprocal relative axial displacement between the first member and the second member, and wherein the first member is coupled to the plunger and configured to transfer motive force thereto along the longitudinal displacement axis.

**25-30.** (canceled)

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