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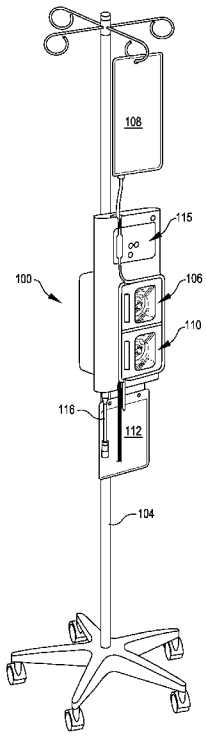
(54) Title: PERISTALTIC PUMP ASSEMBLIES AND SYSTEMS INCORPORATING SUCH PUMP ASSEMBLIES

FIG. 1



(57) Abstract: Peristaltic pump assemblies in which the closing and opening of a pivoting or sliding door is coordinated with movement of the occlusion bed toward and away from the rotor assembly to engage and disengage tubing within the occlusion pathway are disclosed. Linkage mechanisms provided by the interaction of cam surfaces with rollers, as well as bar linkage mechanisms, are disclosed. The linkage mechanism, in addition to providing precise displacement of the occlusion bed, may also provide an over-center feature that enhances safety and pump operation when the door is in a closed position. Latching mechanisms and sensors may be incorporated. Adaptive components such as tubing cassettes routing aspiration and/or infusion tubing in a predetermined configuration to mate with occlusion pathways in aspiration and/or infusion pump assemblies provided in various types of medical devices and control consoles are also provided.

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PERISTALTIC PUMP ASSEMBLIES AND SYSTEMS INCORPORATING SUCH PUMP ASSEMBLIES

FIELD OF THE INVENTION

The present invention relates generally to peristaltic pump housing and component configurations, and peristaltic pump assemblies, in which the closing and opening of a pivoting or sliding door is coordinated with movement of the occlusion bed to engage and disengage tubing within the occlusion pathway. The present invention also relates to systems incorporating peristaltic pump assemblies for use in a wide range of medical device applications.

BACKGROUND OF THE INVENTION

Peristaltic pumps are well known and used in many research, medical and industrial systems and applications for pumping fluids, slurries and other materials. Rotary peristaltic pumps are positive displacement pumps that generally move fluids through flexible tubing positioned in a pathway formed between pump rollers and an occlusion bed by the action of rollers contacting the external surface of the tubing to compress the tubing against the occlusion bed, thereby moving fluids, slurries and other materials through the tubing. The occlusion bed may be moved between an open condition in which tubing may be inserted into the pathway prior to and removed from the pathway following pump operation, and a closed condition in which the tubing is retained between the rollers and the occlusion bed during pumping operations. Many schemes and arrangements have been implemented to facilitate mounting of tubing in the pathway and removal of tubing from the pathway.

U.S. Patent Publication 2009/129944 discloses a peristaltic pump having an occlusion bed slideably mounted in the pump housing. When a pivoting door is opened, the occlusion bed slides away from the rotor assembly to permit mounting of tubing and when the pivoting door is closed, the occlusion bed slides toward the rotor assembly to clamp the tubing in position for pump operation. A rack and pinion arrangement coordinating movement of the sliding occlusion bed with pivoting of the door is disclosed. A sensor may be configured to sense the door condition and disable the peristaltic pump when the door is in an open condition. Additional tube retainer systems for use with peristaltic pumps are described, for

example, in U.S. Patents 4,558,996, 4,025,376, and 6,722,865, European Patent Application EP 0 731 275 and U.S. Patent Publications 2008/175734 and 2007/243088.

Many material removal devices and interventional catheters incorporate mechanical aspiration systems to remove fluid, disease material and/or particulate debris from the site. Some systems incorporate, or are used in conjunction with, other mechanisms such as distal filters, for preventing material dislodged during the procedure or debris generated during the procedure from circulating in the blood stream. Some interventional catheter systems incorporate or are used in conjunction with a fluid infusion system providing delivery of fluids to an interventional site. Interventional catheter systems may also incorporate or be used in conjunction with imaging systems and other types of complementary and/or auxiliary tools and features that facilitate desirable placement and operation of the system during an interventional procedure.

Some interventional catheter systems employ a console-type controller that interfaces directly with interventional catheter components, while some interventional catheter systems employ both a console-type controller that houses non-disposable components such as pumps, drive systems, electrical, electronic, vacuum and fluid control systems, and the like, as well as another intermediate control device that provides operator control options and, in some cases, feedback information. The intermediate control device is typically located at or near a proximal end of the interventional catheter, and may be positioned within or close to the sterile field during a procedure. Interventional catheter systems employing both a console-type controller and an intermediate control device are described, for example, in PCT International Publication WO 2008/042987 A2, the disclosure of which is incorporated herein by reference in its entirety.

During setup of an interventional catheter system employing a control module, an operator typically connects or otherwise operably interfaces components of the interventional catheter assembly, or an intermediate control system generally designed for single patient use, to the reusable console-type control module. In many cases, this involves installing infusion and/or aspiration tubing in the console, interfacing the tubing with pump(s), infusion sources and aspiration receptacles, priming the infusion system, and the like. Providing simple to operate interfaces between infusion and/or aspiration tubing, pumps, sources and receptacles, while also providing accurate and reliable placement of tubing and maintaining appropriate tolerances is essential to pump operation and, ultimately, the success and

outcome of interventional operations. Pump assemblies and systems incorporating these pump assemblies of the present invention are directed to achieving these objectives.

SUMMARY OF THE INVENTION

Peristaltic pump components, component configurations and pump assemblies for use in a wide range of applications, including medical device applications, are disclosed. In general, pump and pump housing component configurations in which the closing and opening of a pivoting or sliding door is coordinated with movement of the occlusion bed to engage and disengage tubing within the occlusion pathway are provided. The component configurations and coordinated movement of a pivoting or sliding door with a slidable occlusion bed provide clearance to conveniently insert and remove tubing from the occlusion pathway, while providing positive and reliable and precise positioning and retention of tubing in the occlusion pathway during operation of pump. The pump components, component configurations and assemblies may be used with a variety of tubing types and pump capacities, providing a wide range of pump pressures, volumes, flow rates, and the like.

Pump assemblies and components of the present invention incorporate a linkage mechanism that coordinates sliding of the occlusion bed toward and away from the pump rotor assembly in concert with movement of a door toward and away from the rotor assembly. In one embodiment, the linkage mechanism coordinates sliding of the occlusion bed in concert with pivoting of a door and is provided by the interaction of cam surfaces with rollers. In this embodiment, cam surfaces may be mounted in a fixed condition on the pivoting door, or on a component mounted on the pivoting door, and rollers configured and positioned to interact with the cam surfaces may be mounted, directly or indirectly, to the occlusion bed. As the door is pivoted from an open condition toward the rotor assembly, curved portions of the cam surfaces contact the rollers to displace the rollers, and the occlusion bed, toward the rotor assembly. A spring mechanism is generally provided to bias the sliding occlusion bed away from the rotor assembly and, as the door is pivoted from a closed condition toward an open condition, curved portions of the cam surfaces contact the rollers and allow the spring mechanism to draw the sliding occlusion bed away from the rotor assembly. The profile and positioning of the cam surfaces may be designed to provide a desired extent of displacement of the sliding occlusion bed, with a desired force, and may also provide an over-center feature that reduces the load and enhances safety and pump

operation as the pivoting door approaches the closed position and when the pivoting door is in the closed position.

In another embodiment in which the linkage mechanism coordinates sliding of the occlusion bed in concert with pivoting of a door, the linkage mechanism is provided as a bar linkage system in which at least two bars are pivotably mounted, directly or indirectly and at opposite ends, to the pivoting door and to the sliding occlusion bed. In this embodiment, one end of each of a set of bars may be mounted for pivoting on a first pivot axis on the pivoting door, or on a component mounted on the pivoting door, and the other end of each of a set of bars may be mounted, directly or indirectly, to the occlusion bed for pivoting on a second pivot axis. As the door is pivoted from an open condition toward the rotor assembly and to a closed position, the linkage bars are displaced, thereby displacing the occlusion bed, toward the rotor assembly. As the door is pivoted from a closed condition toward an open condition and away from the rotor assembly, the linkage bars are displaced away from the rotor assembly, thereby displacing the occlusion bed away from the rotor assembly. The dimensions and placement of the linkage bars may be designed to provide a desired extent of displacement of the sliding occlusion bed, and the pivot axes of the linkage bars and pivoting door may be arranged to provide an over-center feature that reduces the load and enhances safety and pump operation when the pivoting door approaches the closed position and is in the closed position.

In alternative embodiments, pump assemblies comprise a linkage mechanism that coordinates the sliding of the occlusion bed with a door that slides in one direction to provide access to the occlusion pathway and in another direction to prohibit access to the occlusion pathway. The linkage mechanism may, for example, comprise a pair of linkage beams pivotably mounted at one end to a stationary frame member and at another end to a sliding door or cover. The sliding occlusion bed is linked to at least one of the beams so that it follows a lateral component of the path traveled by the bars as the door or cover slides. Thus, as the door or cover slides, the linkage bars pivot, both at their linkage to the sliding door or cover and at their linkage to a stationary frame member, and the sliding occlusion bed moves along a defined lateral path toward and away from the rotor assembly.

Suitable latching mechanisms may be provided to prevent inadvertent opening of the door and disruption of the tubing during pump operation. In one embodiment, one or more magnetic latches may be provided and positioned in mechanical components mounted, directly or indirectly, to the door and to the pump housing, or to a support structure

associated with the pump housing, to provide alignment of the door with the pump housing as well as positive latching. Sensing devices may also be provided to sense when the door is fully closed. Such sensing devices may enable pump operation when the door is fully closed and disable pump operation when the door is fully or partially open.

One or more pump assemblies of the present invention may be used in connection with medical devices incorporating infusion and/or aspiration systems. In one embodiment, one or more pump assemblies is mounted in a control console that houses certain interventional catheter assembly operating systems, such as aspiration and/or infusion systems, and interfaces with a medical device, such as an interventional catheter, to provide suitable aspiration and/or infusion pressures to appropriate interventional catheter lumens, to provide power to the interventional catheter as necessary, and the like. A common control console incorporating one or more pump assemblies of the present invention may be used to operate an aspirating interventional catheter, such as a thrombectomy device, as well as simple infusion catheters and atherectomy and thrombectomy devices that operate using either or both aspiration and infusion systems. The control console may also incorporate other operating and control features, drive systems, power supplies, and the like, that may interface with an interventional catheter assembly.

In another aspect, adaptive components such as tubing cassettes having various configurations may be provided for operating different types of medical devices, such as interventional catheters, using a control console. In one embodiment, for example, a tubing cassette having a housing through which aspiration and/or infusion tubing is conveyed, is provided for interfacing with aspiration and/or infusion systems having pump assemblies provided on a control console. Adaptive tubing cassettes are designed to facilitate positioning of the aspiration and/or infusion tubing in the occlusion pathway. The tubing cassette may route aspiration and/or infusion tubing in a predetermined configuration to mate with the occlusion pathway(s) in aspiration and/or infusion systems on the control console, and may also mate with a mechanical interface provided on the control console to provide stable mounting of the tubing cassette during pump operation. The size, configuration, composition and positioning of tubing loop(s) may be selected based on the type of aspiration and/or infusion system used, the position and configuration of the occlusion pathway, desired pump configurations, operating infusion and/or aspiration volumes and pressures, and the like.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a schematic view of an exemplary interventional catheter control console of the present invention comprising aspiration and infusion systems and showing an infusion source and an aspiration receptacle.

Fig. 2 shows a schematic perspective view of a rotor assembly, sliding occlusion bed, pivoting door and cam mechanism for moving the occlusion bed with respect to the rotor assembly as the pivoting door opens and closes.

Fig. 3 shows a side perspective view of the rotor assembly, sliding occlusion bed, pivoting door and cam mechanism shown in Fig. 2.

Fig. 4 shows a side perspective, enlarged view of a part of the pivoting door, cam and roller mechanism shown in Fig. 3.

Figs. 5A and 5B show enlarged side perspective views of the cam mechanism and mating roller(s) in the door open and door closed conditions.

Fig. 6 shows a top perspective view of a rotor assembly with a tubing section positioned in the occlusion pathway, a sliding occlusion bed, pivoting door, and linkage mechanism for moving the occlusion bed with respect to the rotor assembly as the pivoting door is moved toward and away from the rotor assembly.

Fig. 7 shows a side perspective view of the assembly illustrated in Fig. 6.

Fig. 8 shows a side perspective, enlarged view of a part of the linkage mechanism shown in Figs. 6 and 7.

Figs. 9A and 9B show enlarged side perspective views of the linkage mechanism and the arrangement of the linkage mechanism with respect to the pivoting door and occlusion bed when the pivoting door is in the open and closed condition.

Figs. 12A and 12B show side perspective views of another embodiment of a pump assembly of the present invention having a slidable door linked to a sliding occlusion bed.

Figs. 13A and 13B show side perspective views of yet another embodiment of a pump assembly of the present invention having a slidable door linked to a sliding occlusion bed.

Fig. 12A shows a schematic view illustrating the interface of an adaptive tubing cassette with aspiration and infusion systems incorporated in a control console as illustrated in Fig. 1.

Fig. 12B shows another schematic view illustrating the adaptive tubing cassette shown in Fig. 12A stably mounted in aspiration and infusion systems incorporated in the control console, with exterior doors closed.

Fig. 13A shows a side perspective view of an exemplary interventional catheter tubing cassette adapted for mating with and stably mounting to aspiration and infusion systems incorporated in a control console.

Fig. 13B shows another side view of the exemplary interventional catheter tubing cassette of Fig. 13A illustrating a mechanical mating system for mounting the tubing cassette in a mating receiving structure provided in the console in connection with the aspiration and infusion systems.

Fig.13C shows a perspective view of the exemplary interventional catheter tubing cassette of Fig. 13A with a portion of the housing removed to illustrate the interior of the tubing cassette.

Fig. 14 shows a schematic view illustrating the interface of another adaptive tubing cassette with an aspiration or infusion system incorporated in a control console as illustrated in Fig. 1.

Fig. 15A shows a schematic view illustrating another embodiment of an adaptive tubing cassette suitable for use with an interventional catheter assembly having infusion capability.

Fig. 15B shows a schematic view illustrating another embodiment of an adaptive tubing cassette suitable for use with an interventional catheter assembly having aspiration capability.

Like numbers have been used to designate like parts throughout the drawings to provide a clear understanding of the relationship of the various components and features, even though different views are shown. It will be understood that the appended drawings are not necessarily to scale, and that they present a simplified, schematic view of many aspects of systems and components of the present invention. Specific design features, including dimensions, orientations, locations and configurations of various illustrated components may be modified, for example, for use in various intended applications and environments.

DETAILED DESCRIPTION

Fig. 1 illustrates an exemplary interventional control console 100 mounted, with an accessory infusate reservoir and aspirate receptacle, on a portable IV pole platform 104. In the embodiment illustrated in Fig. 1, control console 100 incorporates an infusion system 106 in fluid communication with an infusate source reservoir 108, such as a sealed fluid bag, and an aspiration system 110 in fluid communication with an aspirate collection receptacle 112.

In the embodiment illustrated, and in preferred embodiments, at least one, and preferably both of the infusion and aspiration systems comprise peristaltic pumps arranged in a vertically stacked relationship. In one preferred embodiment, infusion system 106 comprises a high pressure peristaltic pump capable of infusing fluid at a rate of up to 150 ml/min at a pressure of up to about 160 psi. In another preferred embodiment, aspiration system 110 comprises a generally lower pressure peristaltic pump capable of aspirating liquid and/or liquid/solids mixtures at a rate of at least about 45 ml/min and up to about 90 ml/min at a pressure of up to about (-)15 psi.

Control console 100 may house other system operating systems and components as well, and typically houses complex or bulky operating and control systems that are impractical to provide in single use interventional catheter assemblies, or that cannot be readily sterilized. Control console 100 generally draws power from an external electrical system and generally incorporates a control panel 115 providing a user interface for interacting with operating and control systems housed in control console 100, and for monitoring system operating conditions. In one embodiment, control panel 115 provides a key pad interface for user selection of selectable options and LED indicators for displaying device operational status. Console subassembly 100 may house other system operating systems and components as well, and typically houses complex or bulky operating and control systems that are impractical to provide in single use interventional catheter assemblies, or that cannot be readily sterilized. Console subassembly 100 generally draws power from an external electrical system through electrical cable 116 or may house an independent electrical source.

Infusion system 106 and aspiration system 110 each incorporate at least one pump rotor assembly mounted on a face of the console subassembly, shown in greater detail in Figs. 2, 6 and 7. The pump rotor assembly 120 comprises a rotor housing mounted on a peristaltic pump motor shaft (not shown) for rotation, as a unit, with respect to mounting plate 122. Pump motor is mounted underneath mounting plate and rotor assembly 120 is mounted on peristaltic pump motor shaft. The pump motor shaft, or a portion of it, is generally received in a central enclosure of the pump housing and suitable bearings, flanges, and the like are provided for rotation of pump rotor assembly 120 with respect to mounting plate 122. The rotor housing may comprise an upper plate 121 and a lower plate 123 between which a plurality of rollers 124 are independently and rotatably mounted on rotor

shafts (not shown). The rotor housing is preferably conveniently disassembleable to allow cleaning and maintenance of the rollers, bearings, and the like.

In some embodiments, the position of the rotor housing and rotor assembly may be adjustable with respect to the position of the occlusion pathway and the occlusion bed to facilitate adjustment of the occlusion gap. In yet other embodiments, a sensor may be provided that directly or indirectly senses the relative rotational position of the rotor assembly. This sensor allows the rotor assembly to be preferentially stopped at one of a plurality of predetermined relative angular positions the provides convenient loading of tubing between the pump rotor assembly and the occlusion bed.

Rotor assemblies incorporating three rollers are preferred for use in the present invention, although additional rollers (e.g., four, five, or more) may be used and spaced equidistantly from one another, with their outer surfaces circumscribing a circle. The rollers preferably have equal dimensions and preferably have a diameter from between about 8 and about 15 mm and, in some embodiments, rollers having a diameter of about 11.5 mm are provided. The rollers are preferably constructed from a rigid, hard, durable and chemically resistant material such as a stainless steel material. Rotor assemblies comprising three equidistantly spaced rollers are preferred for use in assemblies and devices of the present invention for ease of loading and operation, and to provide suitable pillow volumes. In general, the same or similar rotor assemblies may be used for both aspiration and infusion pumps.

Figs. 2-5B show one embodiment of an occlusion mechanism for moving an occlusion bed toward and away from the rotor assembly as a door is pivoted toward the closed and open condition, respectively. In the embodiment shown in Fig. 2, rotor assembly 120 is mounted for rotation on support plate 122 and occlusion bed 130 is slidably mounted for movement toward and away from rotor assembly 120, e.g., by sliding on mounting plate 122 or another base plate between rails 133, 134. Rails 133, 134 are preferably aligned parallel to one another and mounted to provide tight clearance with sliding occlusion bed 130, allowing occlusion bed 130 to move along a path toward and away from the rotor assembly. The sliding occlusion bed preferably incorporates grooves that match the configuration and profile of rails 133, 134, or another complementary interface with a cooperating structure that provides consistent and precise sliding of occlusion bed 130 along a path toward and away from rotor assembly 120.

Occlusion bed 130 has curved tubing interface surface 136 that, during peristaltic pump operation and rotation of rotor assembly 120, serves as a stationary curved surface against which the rollers press the tubing to advance and pump fluids in the tubing. The occlusion bed interface surface profile is generally curved along a segment to form a curve substantially similar to, and spaced apart from, the curve formed by a circle circumscribing the outer surfaces of the rollers of the rotor assembly. Occlusion pathway 132 is formed between occlusion bed tubing interface surface 136 and outer surfaces of rotor assembly rollers. A projecting rim 138 is provided at an upper surface of the occlusion bed 130 in the embodiment illustrated in Fig. 2, which overhangs the occlusion pathway and the tubing interface surface and assists in keeping tubing centered in the occlusion pathway during rotation of the rotor assembly and operation of the pump. The occlusion bed geometry is preferably such that occlusion bed surfaces at the end of each pillow segment are tangent to the corresponding roller contact point, and the gap between the tubing and the occlusion bed is constant along the entire pillow segment. Occlusion gaps of between about 0.120 in. and 0.170 in. are suitable for many applications; occlusion gaps of between about 0.150" and about 0.160" are preferred for many embodiments.

Occlusion bed 130 is preferably constructed from a substantially rigid, durable, impact, fatigue and chemically resistant material that is at least somewhat lubricious, at least in the area of the occlusion pathway. Materials having a dynamic coefficient of friction of from about 0.10 to 0.40, and more preferably from about 0.15 to 0.25 are preferred materials for providing at least tubing interface surface 136 and have been found to reduce tubing wear and degradation during operation of the pump. Generally lubricious materials such as acetal resins, including various Delrin® materials, are preferred for use in some embodiments. In some embodiments, an occlusion bed assembly comprises a generally lubricious tubing interface surface stably mounted to a support structure composed of a material having greater stiffness properties, or lower deformation properties, than those of the tubing interface surface. This arrangement has been found to facilitate the high tubing compression forces required for high pressure pumping applications.

Pivoting door 140 is mounted to hinge brackets 144 for pivoting the door toward and away from rotor assembly 120. Hinge bracket(s) 144 are generally mounted to mounting plate 122 or another structure that remains stationary during operation of the motor and during opening and closing of the pivoting door. In the embodiments illustrated in Figs. 2-4, opposing hinge brackets 144 are provided and mount directly to door 140 or indirectly to a

door frame 142 for rotation of the door around pivot axis 146. Hinge brackets 144 may be provided on an integral structure, as shown in Figs. 2-4, or separate brackets may be provided opposite one another for mounting to opposite sides of door 140.

In the embodiment shown in Figs. 2-5B, mating cams 150 are mounted on the underside of pivoting door 140 in the vicinity of hinge brackets 144. As door 140 pivots about pivot axis 146, cams 150 contact rollers 152 mounted in alignment for contact with the respective cam interface surfaces. In the illustrated embodiment, rollers 152 are mounted for rotation around axes 153 in roller mount supports 156. Roller mount supports 156 are mounted in mating cutouts provided opposite corners of occlusion bed 130 and, in the illustrated embodiment, provide continuous surfaces in combination with the occlusion bed. In an alternative embodiment, roller mount supports may be provided directly in a portion of the occlusion bed itself as integral components of the occlusion bed. Additional alternative structures and constructions may be contemplated and used, provided that the rollers and roller mount supports are mounted for movement (e.g., displacement or translation) with occlusion bed 130. Cams and rollers are generally high wear components, made from rigid, hard, highly impact, fatigue and chemically resistant materials such as stainless steels. The roller mount supports may provide a highly rigid support structure having greater stiffness properties than those of the tubing interface surface of occlusion bed 130, as described previously. This arrangement is particularly suitable for use in pump assemblies used in high pressure pumping applications.

Fig. 4 shows an enlarged view of hinge bracket 144, occlusion bed 130 slidably retained along rail 124, pivoting door pivot axis 146, roller mount support 156, roller 152 and cam 150 in the door open, occlusion pathway open condition. This embodiment also shows a spring 160 biasing occlusion bed 130 and stationary mounting bracket 144 toward hinge bracket(s) 144 so that, as the door 140 is pivoted toward a closed position and the occlusion bed 130 is displaced toward the rotor assembly by action of the cam surfaces on rollers 142, the cam and roller surfaces remain in positive contact and tension. During opening of the pivoting door 140 and when the pivoting door is in an open condition, the spring mechanism 160, which may be any type of spring or biasing mechanism, biases the occlusion bed 130 and components associated with the occlusion bed, toward the hinge bracket to maintain the appropriate separation between the occlusion bed tubing contact surface 136 and the rotor assembly 120, allowing removal of tubing from and insertion of tubing into the occlusion pathway 132. During closing of the pivoting door and when the pivoting door is in a closed

position, the spring mechanism is extended and maintains tension on the occlusion bed as the occlusion bed is displaced toward the rotor assembly by the action of the cam surfaces on rollers 142.

Fig. 4 also illustrates a system for adjusting the dimension of the occlusion gap or passageway. Adjustment of the occlusion gap may be desirable to accommodate different sizes and types of tubing, and to modify the pressures exerted on the tubing during operation of the pump. In this embodiment, hinge bracket(s) 144 is mounted on or provided integrally with an adjustment plate 164 mounted directly, or indirectly, to support plate 122. Adjustment plate 164 thus remains stationary with respect to support plate 122 and roller assembly during pivoting of the door and displacement of the occlusion bed. Adjustment plate 164 may be mounted in a cavity, or slot, permitting displacement of the adjustment plate toward and away from the rotor assembly. One or more set screws 166 may be provided for mounting adjustment plate 164 in a desired location and setting the desired occlusion gap for a particular device, interventional procedure, tubing type, pump pressure or volume, or the like, thereby changing the location of the cam surfaces and, through the spring mechanism, additionally adjusting the location of the roller surfaces, roller mount supports and occlusion bed with respect to the rotor assembly.

Figs. 5A and 5B show an enlarged, partially cut-away view of the surfaces of cam 150 interfacing with the mating surfaces of roller 152 during closing of the door (Fig. 5A) and when the door is fully closed (Fig. 5B). The cam surfaces 155 that contact the roller surfaces during opening and closing of the pivoting door are generally curved, or may comprise a plurality of generally short linear sections that, in combination, approximate a curved surface. The profile of the cam surfaces may be chosen, and adjusted, to customize the force curve and the force generated by interaction of the cam surface with the roller. In one embodiment, the linkage mechanism provided by the interaction of the cam and roller surfaces provides a linear actuation relationship between the angle of the pivoting door and the position of the occlusion bed. This arrangement requires progressively greater force to pivot the door as it approaches the closed position and to move the occlusion bed as it contacts tubing in the occlusion pathway.

In another embodiment, the linkage mechanism provides a non-linear actuation relationship between the angle of the pivoting door and the position of the occlusion bed. Non-linear actuation relationships may be designed to provide an over-center feature that results in progressively greater mechanical advantage (i.e. progressively less force required

for door pivoting and occlusion bed movement) as the door approaches the closed position and the occlusion bed approaches, and contacts, tubing in the occlusion pathway. Providing a flat cam surface 159 at the location where the roller contacts the cam when the door is in a closed position, as shown in Fig. 5B, provides an over-center design, which facilitates positive positioning of the door when closed and minimizes the chance of the door opening inadvertently during operation of the pump.

Latching mechanism(s) may also be provided to provide positive positioning of the door when closed and to reduce the chance of the door opening inadvertently during pump operation. Many different types of latching mechanisms may be used including, for example, magnetic latches. In the embodiments illustrated in Figs. 2 and 3, magnets may be mounted in posts 165 positioned opposite the roller assembly 120 from occlusion bed 130, with additional magnets mounted in a door framework or posts 168. Posts 165 and 168 are positioned in proximity to one another when door 140 is in a closed position, with the magnets serving a latching function to maintain the door in the closed position until sufficient force is exerted to break the magnetic attraction. In the embodiment illustrated in Fig. 2, posts 165 are independent of one another; in alternative embodiments, the posts may be provided on a unitary structure mounted directly or indirectly to mounting plate 122 and having a structure intermediate the posts. The intermediate structure may provide support and/or guidance for tubing during operation of the rotor assembly and pump.

One or more sensors may also be provided in pump assemblies of the present invention for sensing when the pivoting door is in a closed and/or open condition. Suitable sensors are well known in the art. The sensor(s) may communicate with control mechanisms to provide safety and control features. In one embodiment, for example, movement of the rotor assembly is enabled only when the pivoting door is fully closed and the sensor confirms the closed condition. In another embodiment, movement of the rotor assembly is disabled in all door positions other than when the door is fully closed and the sensor(s) activated.

Figs. 6-9B schematically illustrate another embodiment of components and a system for moving an occlusion bed toward and away from the rotor assembly as a door is pivoted toward and away from the rotor assembly to a closed and an open condition. Unless noted otherwise in the disclosure provided below, components that are similar to or common with those described above in connection with Figs. 2-5B are labeled similarly and are not described in detail below.

In the embodiment shown in Figs. 6 and 7, rotor assembly 120 is mounted for rotation with respect to mounting plate 122. Occlusion bed 130 is slidably mounted for movement toward and away from rotor assembly 120, e.g., by sliding on mounting plate 122, or another base structure, between rails 133, 134. Occlusion bed 130 has curved tubing interface surface 136 that, during peristaltic pump operation and rotation of rotor assembly 120, serves as a stationary curved surface against which the rollers press tubing 155 loaded in the occlusion pathway to advance and pump fluids in the tubing. The occlusion bed geometry and properties are as described previously in this application. Door 140 is mounted to hinge brackets 144 for pivoting the door toward and away from rotor assembly 120. Hinge bracket(s) 144 are generally mounted to mounting plate 122 or another structure that remains stationary during operation of the motor. In the embodiments illustrated in Figs. 6 and 7, opposing hinge brackets 144 are provided and mount directly to door 140 or indirectly to a door frame 142 for rotation of the door around pivot axis 146.

A linkage assembly provides the connection between the pivoting door and sliding occlusion bed in the embodiments shown in Figs. 6-9B. In the embodiment illustrated in Fig. 6, two occlusion bed frame members 172, 174 incorporating mounting brackets 173, 175 that contact (directly or indirectly) and mount to surfaces of sliding occlusion bed 130 on opposite sides of a centerline of the occlusion bed. In an alternative embodiment, a unitary occlusion bed frame member may contact a surface of sliding occlusion bed 130 opposite the occlusion surface substantially along its length and incorporate mounting brackets similar to those shown in Fig. 6. The mounting brackets or occlusion bed frame member may provide a highly rigid support structure having greater stiffness properties than those of the tubing interface surface of occlusion bed 130, as described previously, and may form part of an integral occlusion bed assembly.

Mounting brackets 173, 175 provide pivotable mounting of one end of linkage bars 176, 178 for pivoting around a common pivot axis 180. The opposite ends of linkage bars 176, 178 are pivotably mounted in brackets 177, 179 associated with the door and/or door frame around a common pivot axis 185. Shoulder screws mounting each end of each of the linkage bars to the appropriate bracket may act as both hinges and bearings. As the door is pivoted toward the rotor assembly and toward a closed position (e.g., following placement of tubing in the occlusion pathway), the door brackets, linkage bars, occlusion bed frame and occlusion bed move toward the rotor assembly to position the occlusion bed against the tubing for operation of the pump. As the door is pivoted away from the rotor assembly

toward an open position (e.g., following a pumping operation), the door brackets, linkage bars, occlusion bed frame and occlusion bed move away from the rotor assembly to draw the occlusion bed away from the tubing, allowing removal of the tubing from the occlusion pathway.

The hinge point positions of the linkage bars and the door bracket may be adjusted, as desired, to change the force curve and to provide a linear or a non-linear actuation relationship between the angle of the pivoting door and the position of the occlusion bed. Figs. 9A and 9B show one embodiment of a preferred arrangement of rotational axes of the bar linkage and pivoting door that provides an over-center feature and non-linear actuation relationship between the angle of the pivoting door and the position of the occlusion bed. In the door open condition, when the door is rotated away from the rotor assembly, as shown in Fig. 9A, the occlusion bed pathway is open and the occlusion bed is positioned generally away from the rotor assembly. In this door open condition, the pivot axis 181 of the bar linkage at the door bracket is on one side of, seen as above in Fig. 9A, the pivot axis 146 of the door in bracket 144, while the pivot axis 180 of the bar linkage at the occlusion bed frame bracket 172 is on the other side of the pivot axis 146 of, shown as below in Fig. 9A. In the door closed condition, as shown in Fig. 9B, when the door is rotated toward the rotor assembly and the occlusion bed passage is closed against tubing, both of bar linkage pivot axes 180, 185 are located on the same side of, shown as below, the door pivot axis 146. In another embodiment, the pivot axis 181 of the bar linkage 176 at the door bracket is positioned below a line joining the pivot axis 146 of the door 144 and the pivot axis 180 of the bar linkage at the occlusion bed frame bracket when the door is in a closed position. This provides an "over-center" feature that results in progressively greater mechanical advantage (i.e. progressively less force required for door pivoting and occlusion bed movement) as the door approaches the close position and the occlusion bed approaches, and contacts, tubing in the occlusion pathway, and facilitates positive and secure positioning of the door in the closed condition, reducing the chance of the door opening during operation of the pump.

Pump assemblies incorporating the linkage mechanism described with reference to Figs. 6-9B may additionally incorporate an adjustment mechanism for changing the occlusion bed dimensions or gap, a latching mechanism, one or more sensor(s), and the like, all as described in connection with the pump assemblies previously described herein.

Figs. 10A-B and 11A-B schematically illustrate alternative embodiments of linkage mechanisms for moving an occlusion bed toward and away from the rotor assembly as a door

slides between open and closed positions, exposing and covering the occlusion pathway, respectively. In the embodiments shown in Figs. 10A-B and 11A-B, occlusion bed 130 having curved tubing interface surface 136 is slidably mounted for movement toward and away from a rotor assembly (not shown) by sliding with respect to mounting plate 122 between rails 133, 134, as described previously. One or more pairs of linkage beams 192A, 192B, 194A, 194B are pivotably mounted, directly or indirectly, at one end to sliding door 190 and at the other end to rails 133, 134 or another structure that remains stationary as the occlusion bed and sliding door travel.

One or more of the linkage beams, and preferably at least one pair of linkage beams, is also linked to sliding occlusion bed 130. In the embodiment illustrated in Figs. 10A and 10B, at least one pair of linkage beams, e.g., 192A, 192B, incorporates a slot 196 in which a pin 198 or another structure mounted to or forming part of occlusion bed 130 travels. Thus, in this embodiment, door 190 may be positioned to close or prohibit access to the occlusion pathway in a closed position, shown in Fig. 10A, when the linkage beams are angled in one direction. Door 190 slides, to the right in the embodiments shown in Figs. 10A and 10B, to provide access to the occlusion bed and expose the occlusion pathway. As the door slides to the open position, the linkage beams pivot through an angular path and pin 198 slides in slot 196 to translate occlusion bed 130 (e.g., away from the rotor), providing access to the occlusion pathway. Sliding of door 190 in the opposite direction reverses the motions, translates occlusion bed 130 in the opposite direction (e.g., toward the rotor), and covers the occlusion pathway.

In the embodiment illustrated in Figs. 11A and 11B, at least one of the linkage beams, and preferably at least one pair of linkage beams, e.g. 194A, 194B, is mounted to another pivoting linkage 199 that is also pivotably mounted, directly or indirectly, to occlusion bed 130. Thus, in this embodiment, door 190 may be positioned to close or prohibit access to the occlusion pathway in a closed position, shown in Fig. 11A, when the linkage beams are angled in one direction. Door 190 slides, to the right in the embodiments shown in Figs. 11A and 11B, to provide access to the occlusion bed and expose the occlusion pathway. As the door slides to the open position, the associated linkage beam pivots with respect to pivoting linkage 199, and then slides the pivoting linkage 199 and occlusion bed 130 in the direction of motion of door 190. By this combination of pivoting and translation of pivoting linkage 199 with sliding of door 190 toward an open position and then opposite direction, the occlusion bed is translated with respect to support plate 122 (and the rotor) to open and close

the occlusion pathway. Sliding of door 190 in the opposite direction reverses the motions, translates occlusion bed 130 in the opposite direction (e.g., toward the rotor), to close and cover the occlusion pathway.

Pump assemblies of the present invention may be incorporated in medical devices, control consoles, and the like, as illustrated in Fig. 1 herein. Adaptive tubing components and tubing cassettes may be provided in connection with such devices and the pumps described herein to facilitate positioning of appropriate tubing within the pump assembly occlusion pathways. Exemplary adaptive tubing components and their installation in pump assemblies, control consoles and medical devices of the present invention are illustrated in Figs. 12A and 12B. Adaptive tubing cassette 240 interfaces with the aspiration and/or infusion systems provided in control module 100 and comprises a housing component 242 and two preformed tubing loops 244, 246 sized and configured to insert into and mate with infusion and aspiration systems housed in control console 100. Tubing loops 244, 246, in the embodiment shown, are sized and configured to insert into and mate with a tubing pathway, or occlusion bed pathway 132, provided in peristaltic pump assemblies housed in the control console. Infusion tubing loop 244 is in fluid communication with infusion tubing and infusate source tubing 254, which is connected or connectable to an infusate source or reservoir. Aspiration tubing loop 246 is in fluid communication with aspiration tubing 256 connected or connectable to aspirate collection receptacle. Adaptive tubing cassette housing component 242 provides a structure for grasping and manipulation by an operator and also incorporates an interface structure sized and configured to mate, such as mechanically and/or electronically, with a receiving structure provided on control console 100 in proximity to the aspiration and/or infusion systems.

Figs. 12A and 12B show enlarged schematic diagrams illustrating an adaptive tubing cassette 240 in position for mounting (Fig. 12A) and mounted (Fig. 12B) in infusion and aspiration systems on control console 100, and Figs. 13A-13C show various views of adaptive tubing cassette 240. During operation of an associated medical device, such as an interventional catheter assembly, infusion tubing 254 accesses the infusate source(s) and, prior to entry into tubing cassette housing 242, may incorporate an optional valve 255 (See, e.g., Fig. 13C) comprising a self sealing membrane for withdrawing fluids (or gas) from the infusion tubing line 254, or for introducing fluids to the infusion tubing line 254. Suitable bubble detector(s) may also be provided in conjunction with infusion tubing to detect and/or prevent entrainment of bubbles that would be harmful to patients. Infusion tubing 254 is in

sealed fluidic communication with preformed infusion tubing loop 244 at an infusate entry portion 243 of preformed infusion tubing loop 244, and infusion tubing loop 244 is in sealed fluidic communication with interventional catheter infusion tubing 234 at an infusate exit portion 245 of preformed infusion tubing loop 244.

In some embodiments, infusion tubing 254, preformed infusion tubing loop 244 and interventional catheter infusion tubing 234 may comprise tubing having the same or similar properties and dimensions. In other embodiments, such as when infusion system 106 comprises a high pressure infusion pump, preformed infusion tubing loop 244 comprises a thicker walled, generally stiffer tubing material than the tubing of infusion tubing 254 or 234. Preformed infusion tubing loop 244 is configured to mate with a pump assembly occlusion pathway 132 in infusion system 106 that, when the pump is operating, retains the tubing as pump rollers operate to advance infusate through the tubing at a generally high pressure and volume. In one embodiment, desired infusate rates of up to about 150 ml/min at infusate pressures of up to 160 psi are provided by infusion pump system 106. Preformed infusion tubing loop 244 is designed to withstand the generally high infusate pressures generated at infusion pump system 106.

Aspiration tubing loop 246 is configured to mate with a pump assembly occlusion pathway 132 in aspiration system 110 that, when the pump is operating, retains the tubing as pump rollers operate to advance aspirate through the tubing at generally moderate pressures and volumes. In one embodiment, desired aspiration rates of up to about 90 ml/min at aspiration pressures of up to 25 psi are provided by infusion pump system 106. In some embodiments, aspiration tubing 256 and preformed aspiration tubing loop 246 may comprise tubing having the same or similar properties and dimensions. Preformed aspiration tubing loop 246 generally comprises a thinner walled, generally more flexible tubing than preformed infusion tubing loop 244.

In some embodiments, preformed tubing loops 244 and 246 comprise different tubing materials and have a different configuration, as shown. As can be seen in Figs. 13A and 13B, for example, the outer diameter of preformed infusion tubing loop 244 is larger than the outer diameter of preformed aspiration tubing loop 246. In addition, preformed infusion tubing loop 244 extends a greater distance d_i from an edge of housing 242 than the distance d_a of preformed aspiration tubing loop 246 from an edge of housing 242. The width of preformed infusion tubing loop 244 W_i may also be less than the width W_a of preformed aspiration tubing loop 246.

Tubing cassette housing 242 has a size and configuration suitable for housing the various infusate and aspirate tubing components in a convenient and kink-free manner and provides a convenient, exposed user grasping surface. The user grasping surface may incorporate a handle 250 in a central portion of the housing, between preformed tubing loops 244 and 246 and oriented for grasping on a surface substantially orthogonal to the plane of the preformed tubing loops. Handle 250 may be formed by adjacent recesses, or indentations, providing convenient access and grasping.

The face of tubing cassette housing 242 generally opposite handle 250, which is substantially orthogonal to the plane of preformed tubing loops on the opposite side, preferably incorporates at least one mechanism for detachably mating with the control console in the area of the infusion and/or aspiration systems. This mating system may comprise a mechanical mating structure(s) provided on tubing cassette housing 242 such as keyed recesses 255, sized and configured to interlock with mating structures provided on the control console in proximity to infusion and aspiration systems 106, 110, respectively. Keyed recesses 255 and the mating structures provided on the control console provide a stable, and preferably detachable mounting of tubing cassette housing 242 on the control console. While mechanically interlocking structures are illustrated and described, it will be appreciated that other types of mechanical and/or electronic structures may provide the desired detachable interlocking features.

Fig. 13C illustrates, in addition to the various fluid tubing components residing in adaptive tubing cassette 240, an electrical or electronic interface component 260. Electronic interface component 260 may comprise a data storage device 261 providing authentication and/or operating instruction protocols and cable 262 terminating in an interface 263. Interface 263 may communicate following connection to a mating interface provided on control console 100 or an intermediate interface component.

Fig. 14 illustrates an alternative embodiment of a preformed tubing cassette 280 according to the present invention comprising housing 282 having a centrally positioned handle 283 and a single preformed tubing loop 284. In alternative embodiments, tubing loop 284 may be sized and configured for mating with a tubing pathway formed as part of an infusion or aspiration system. This type of preformed tubing cassette having a single preformed tubing loop may be used, for example, with interventional catheter assemblies having either infusion or aspiration capabilities, but not both, and may otherwise interface

with control console 100 similarly to the interface of adaptive tubing cassette 240, described above.

Figs. 13A and 13B illustrate alternative embodiments of adaptive tubing cassettes 290 and 300, respectively, having housings 292 and 302, respectively, sized and configured for detachably mating with the control console in the area of the infusion and/or aspiration system(s). Adaptive tubing cassettes 290 and 300 have a central handle 294, 304 for grasping and incorporate preformed tubing loops 296, 306, respectively. Adaptive tubing cassette 290 is designed for use with an infusion (only) interventional catheter assembly; adaptive tubing cassette 300 is designed for use with an aspiration (only) interventional catheter assembly.

While the present invention has been described above with reference to the accompanying drawings in which particular embodiments are shown and explained, it is to be understood that persons skilled in the art may modify the embodiments described herein without departing from the spirit and broad scope of the invention. Accordingly, the descriptions provided above are considered as being illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting the scope of the invention.

We Claim:

1. A peristaltic pump assembly comprising a rotor assembly having a plurality of rollers mounted in a rotatable housing in operable communication with a drive motor for rotating the rotor assembly; an occlusion bed slidably mounted in a spaced apart relationship to the rotor assembly and having a curved surface facing the rotor assembly that forms an occlusion surface for tubing retained in an occlusion pathway during operation of the peristaltic pump; a pivoting or sliding door adjustable between an open condition providing access to the occlusion pathway and a closed condition in which access to the occlusion pathway is blocked; wherein a linkage mechanism is provided that moves the occlusion bed in concert with the pivoting or sliding of the door.

2. The peristaltic pump assembly of claim 1, wherein the door is a pivoting door and the linkage mechanism comprises a pair of cam surfaces mounted on the door and a pair of rollers mounted directly or indirectly to the occlusion bed and positioned to contact the cam surfaces as the pivoting door is closed and opened.

3. The peristaltic pump assembly of claim 2, wherein the cam surfaces are curved over a portion that contacts the rollers during closing and opening of the pivoting door and have a different curved profile or a flat profile that contacts the rollers at the far end of travel when the pivoting door is closed.

4. The peristaltic pump assembly of claim 1, wherein the linkage mechanism comprises a pair of bars pivotably mounted at one end to the door and at the other end, directly or indirectly, to the occlusion bed.

5. The peristaltic pump assembly of claim 1, wherein the linkage mechanism provides an over-center feature that facilitates positive positioning of the door in a closed position.

6. The peristaltic pump assembly of claim 1, wherein the linkage mechanism provides a linear actuation relationship between the position of the door and the position of the occlusion bed.

7. The peristaltic pump assembly of claim 1, wherein the linkage mechanism provides a non-linear actuation relationship between the position of the door and the position of the occlusion bed.

8. The peristaltic pump assembly of claim 7, wherein progressively less force is required to move the door as the door approaches the closed position.

9. The peristaltic pump assembly of claim 1, additionally comprising a mechanical latch that maintains the door in a closed position.

10. The peristaltic pump assembly of claim 1, additionally comprising a magnetic latch that maintains the door in a closed position.

11. The peristaltic pump assembly of claim 1, additionally comprising a latch that maintains the door in an open position.

12. The peristaltic pump assembly of claim 1, additionally comprising a sensor that senses when the door is in a closed position and allows pump motor operation when door is closed.

13. The peristaltic pump assembly of claim 1, additionally comprising a sensor that senses when the door is in an open position and disables pump operation when the door is open.

14. The peristaltic pump assembly of claim 1, wherein the occlusion surface comprises a material having a dynamic coefficient of friction in the range of 0.15-0.25.

15. The peristaltic pump assembly of claim 1, wherein the occlusion surface contacts a support surface having greater stiffness properties than those of the material forming the occlusion surface.

16. The peristaltic pump assembly of claim 1, wherein the relative position between the axis of rotation of the rotor assembly and the occlusion surface is adjustable.

17. The peristaltic pump assembly of claim 1, additionally comprising a sensor that senses the relative rotational position of the rotor assembly and stops the rotor assembly at one of a plurality of predetermined relative angular positions.

18. A control console incorporating at least one peristaltic pump assembly of claim 1.

19. A control console of claim 18 incorporating two peristaltic pump assemblies of claim 1, wherein one of the peristaltic pump assemblies comprises a high pressure peristaltic pump capable of infusing fluid at a pressure of up to 160 psi and another peristaltic pump assembly comprises a lower pressure peristaltic pump capable of aspirating liquid or liquid/solids mixtures at a pressure of up to (-)15psi.

FIG. 1

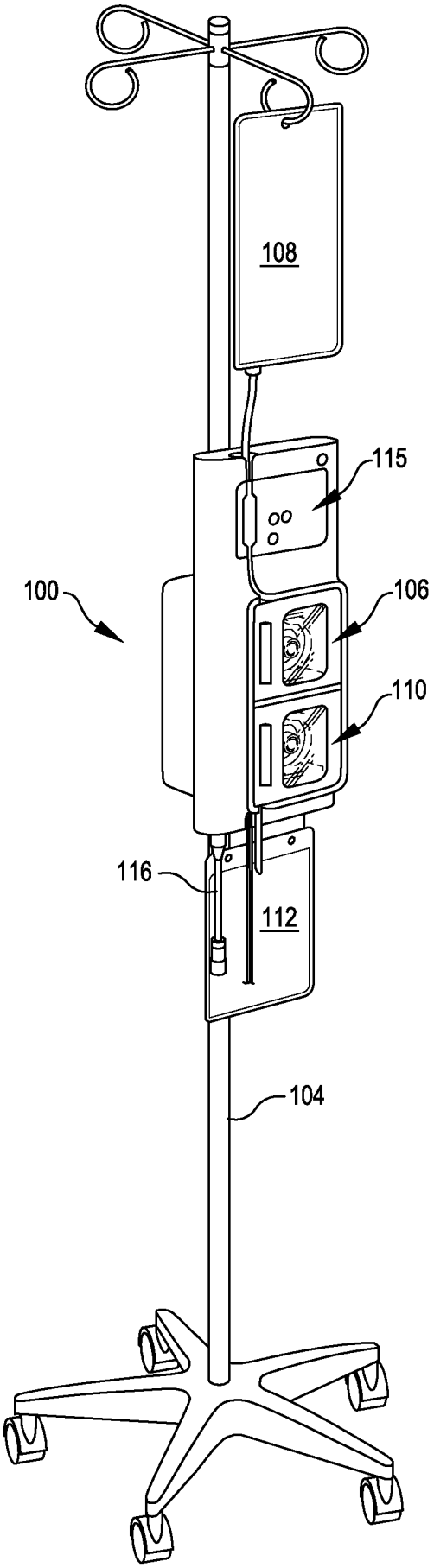

FIG. 2

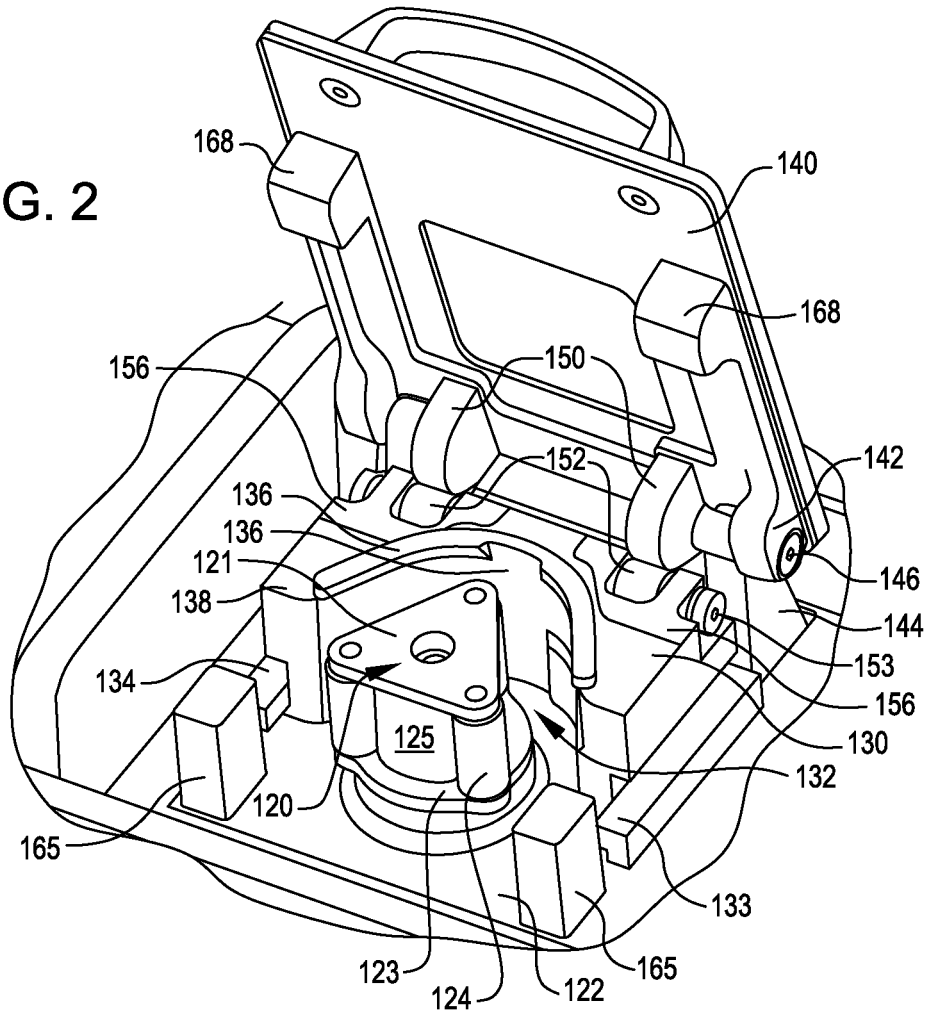
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FIG. 3

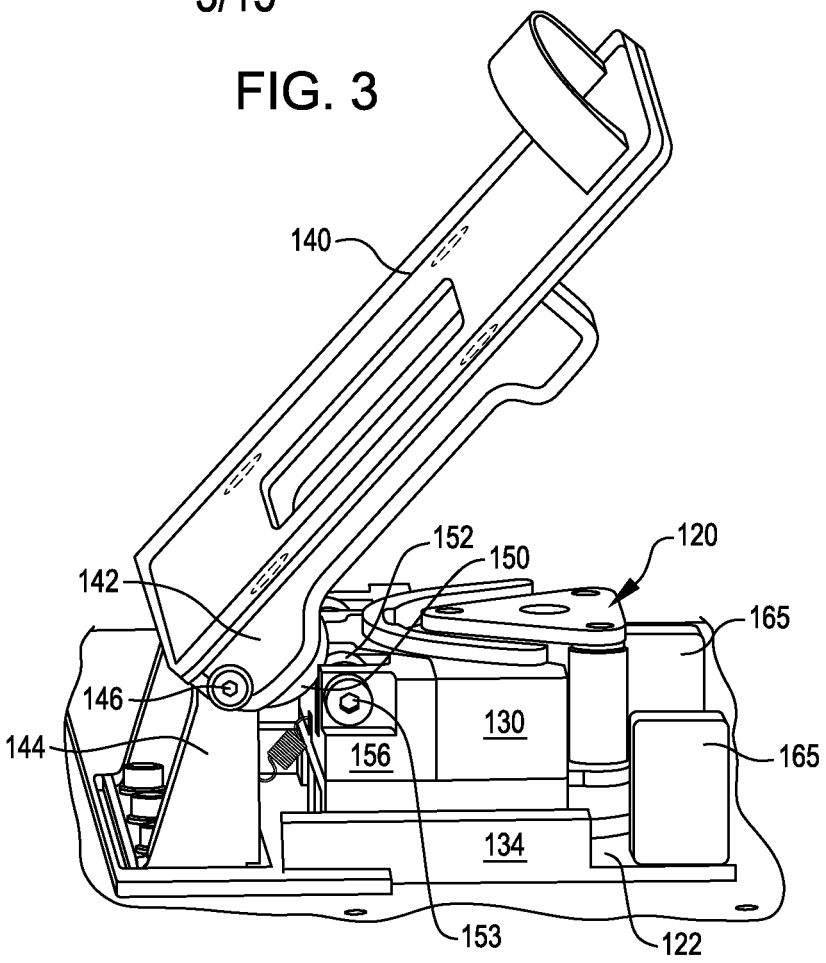
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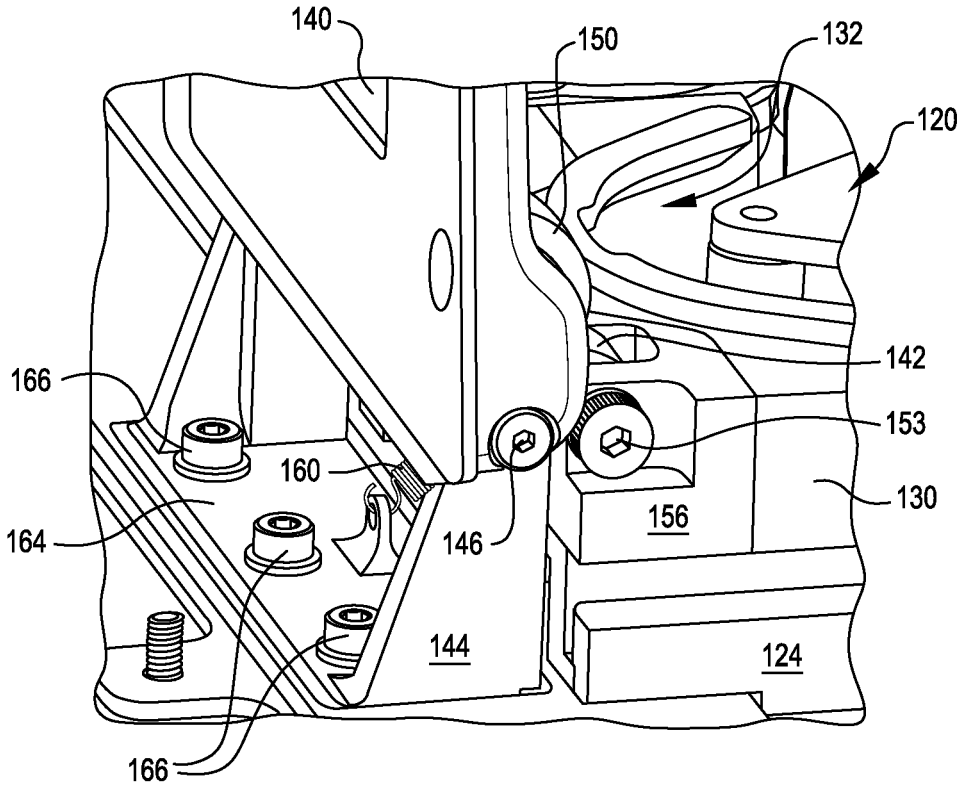
FIG. 4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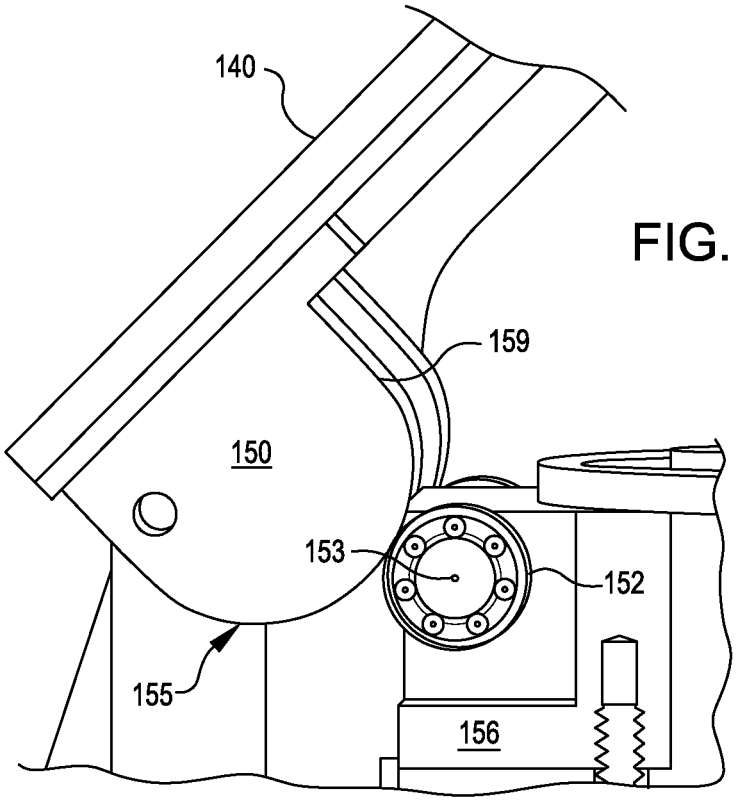

FIG. 5A

FIG. 5B

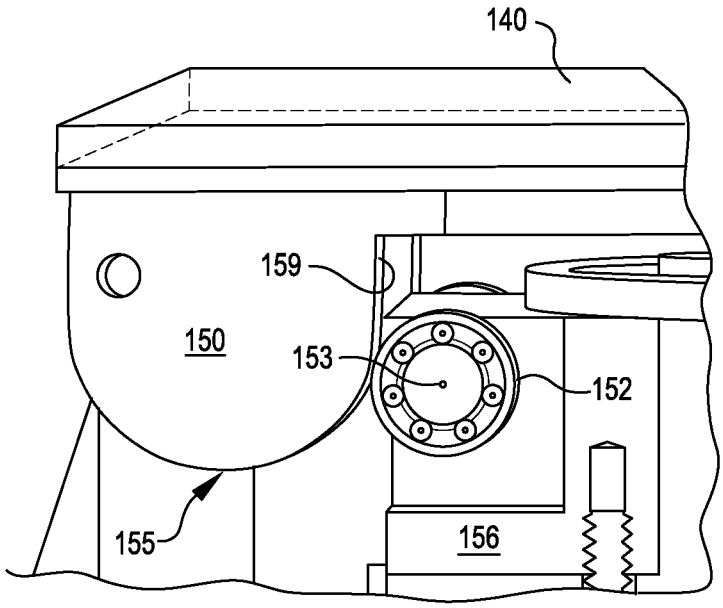

FIG. 6

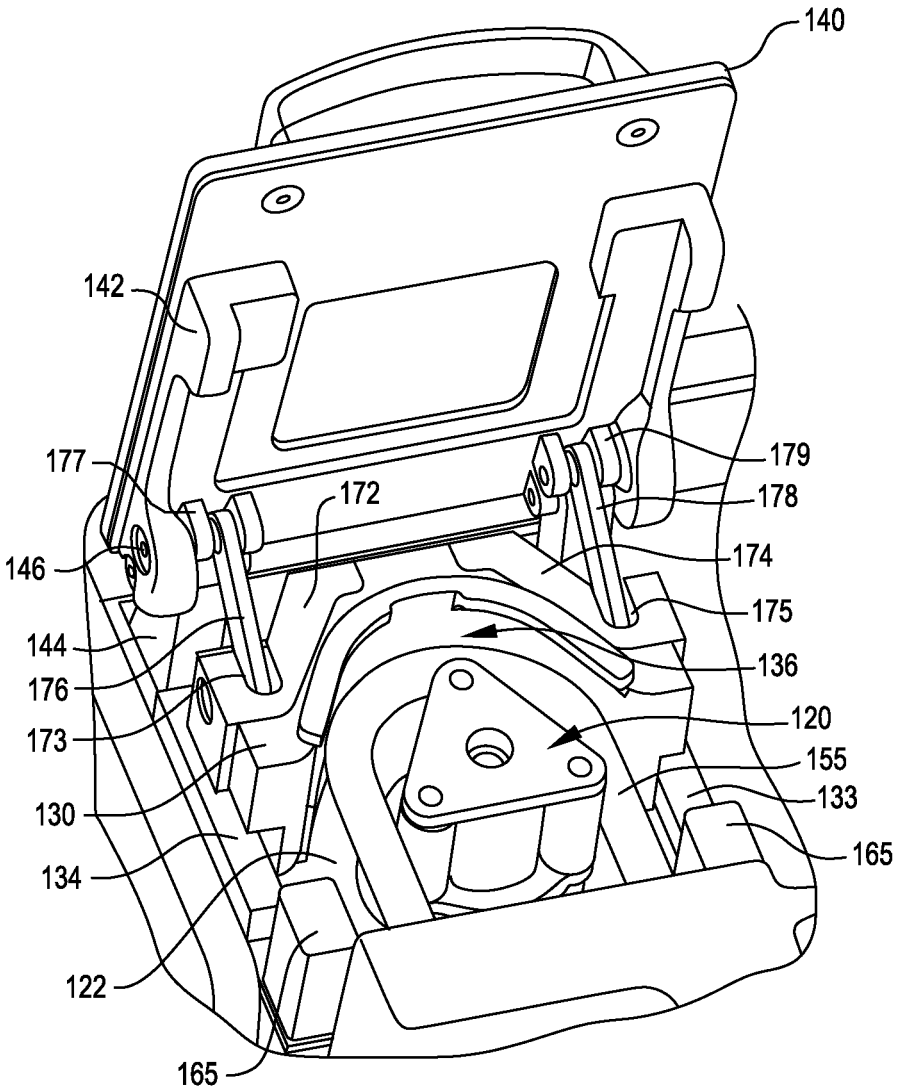
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FIG. 7

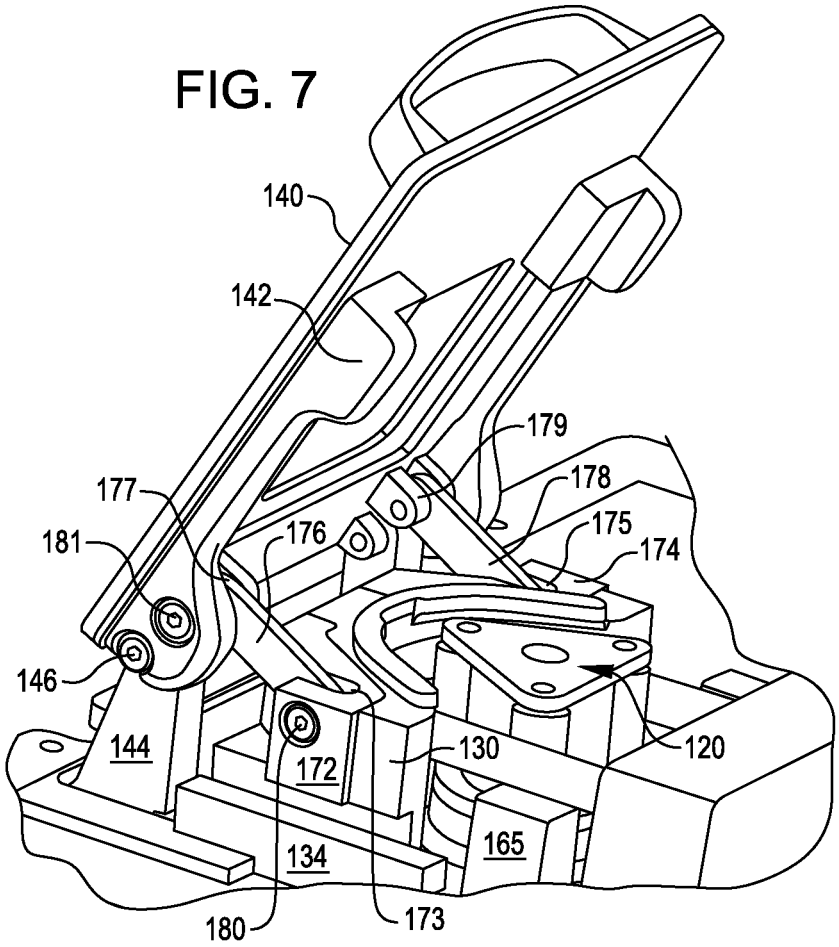
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FIG. 8

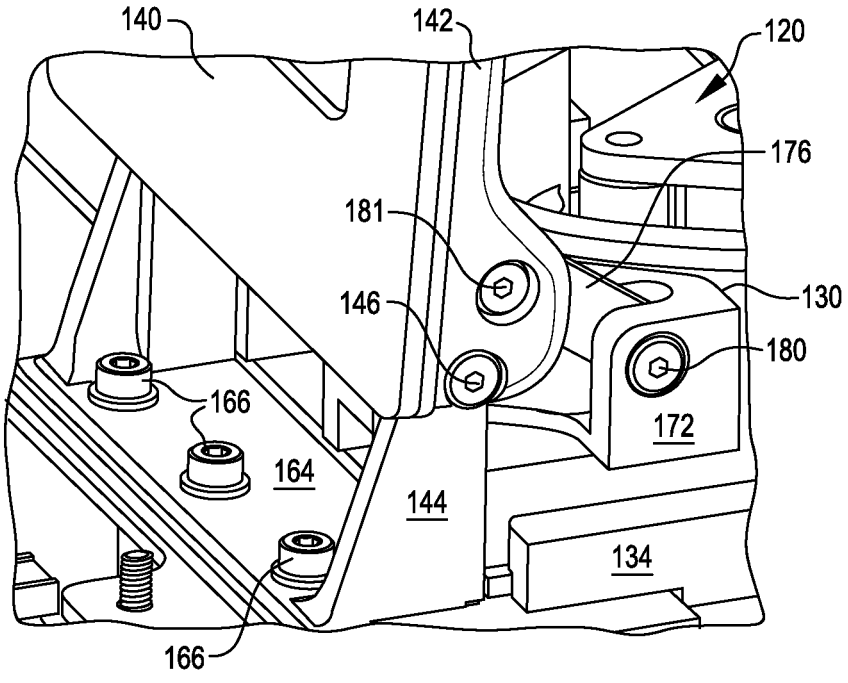
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FIG. 9A

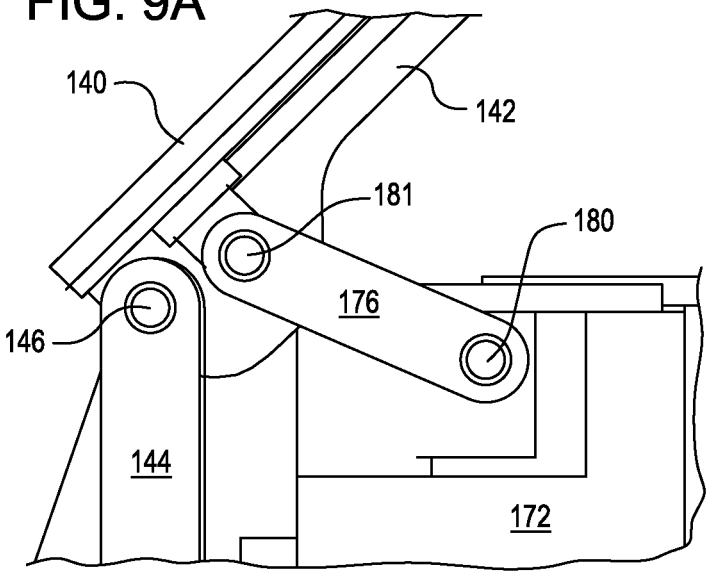


FIG. 9B

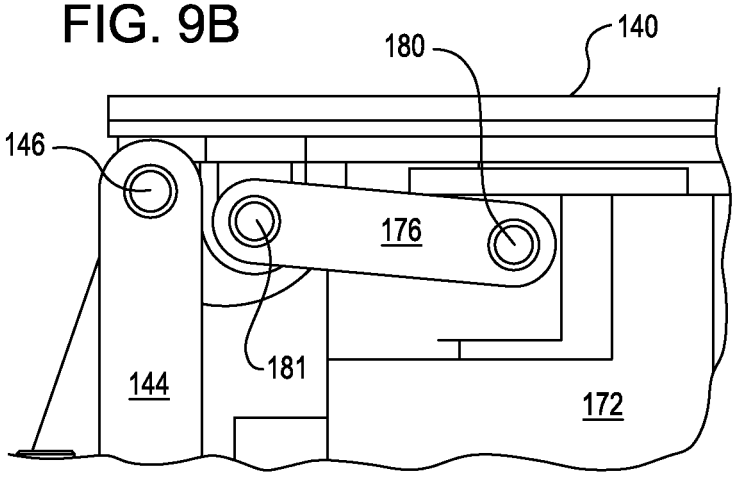


FIG. 10A

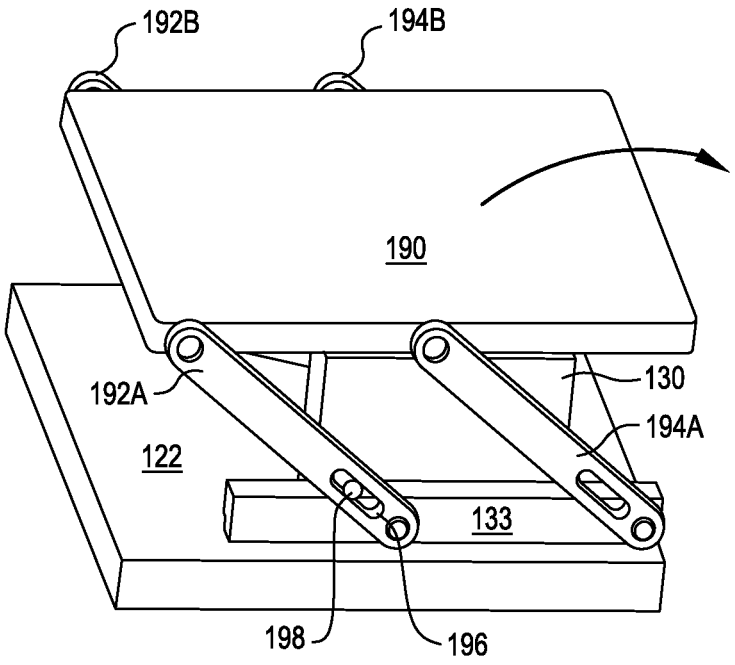


FIG. 10B

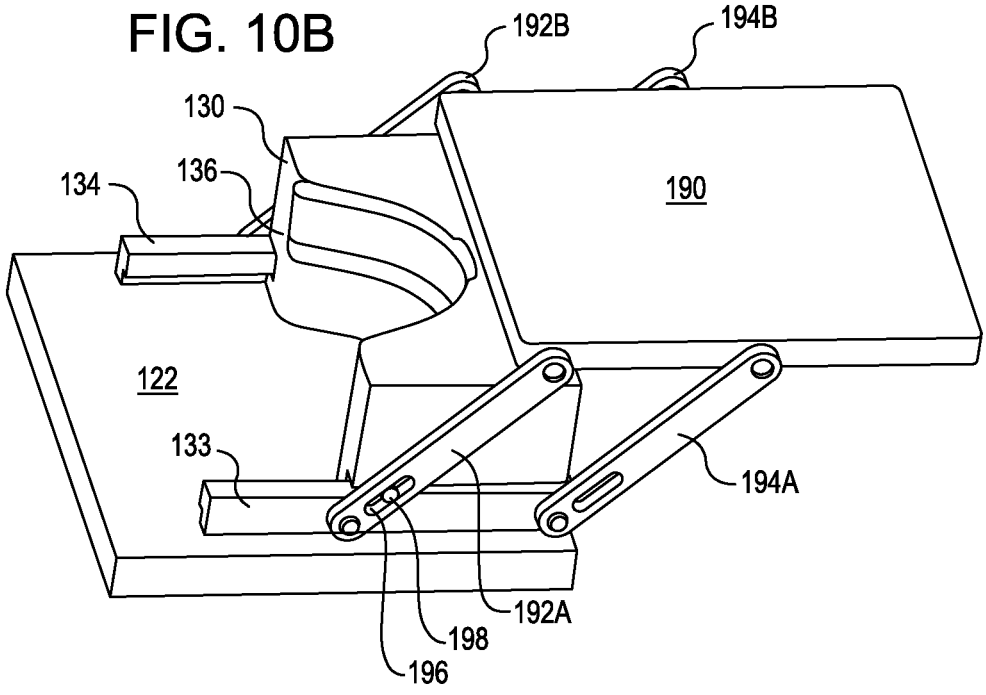


FIG. 11A

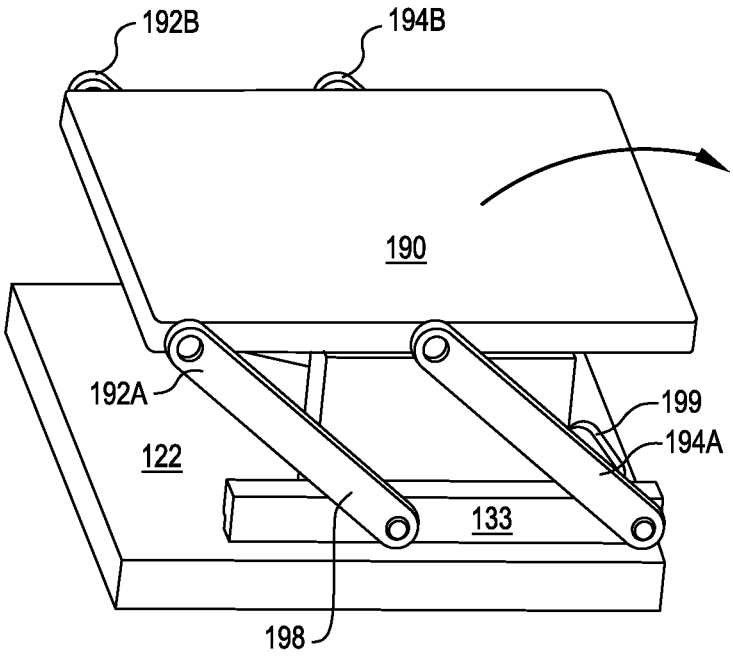


FIG. 11B

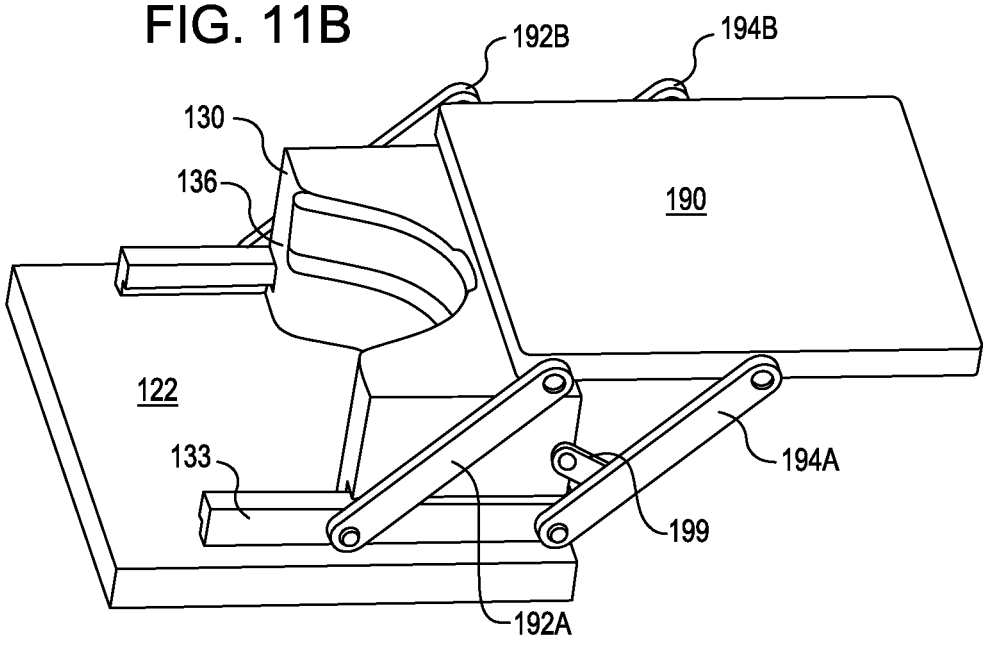


FIG.12A

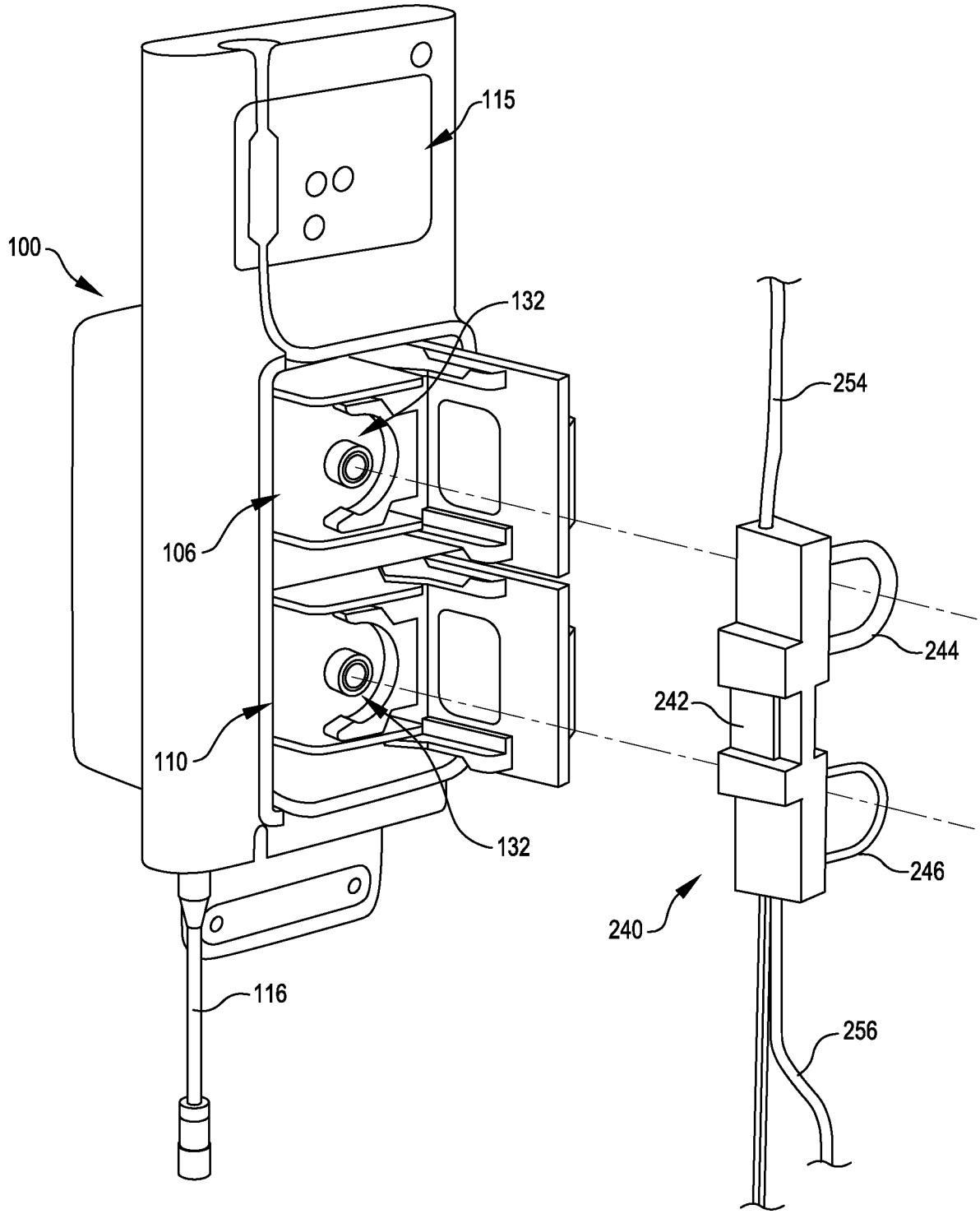


FIG. 12B

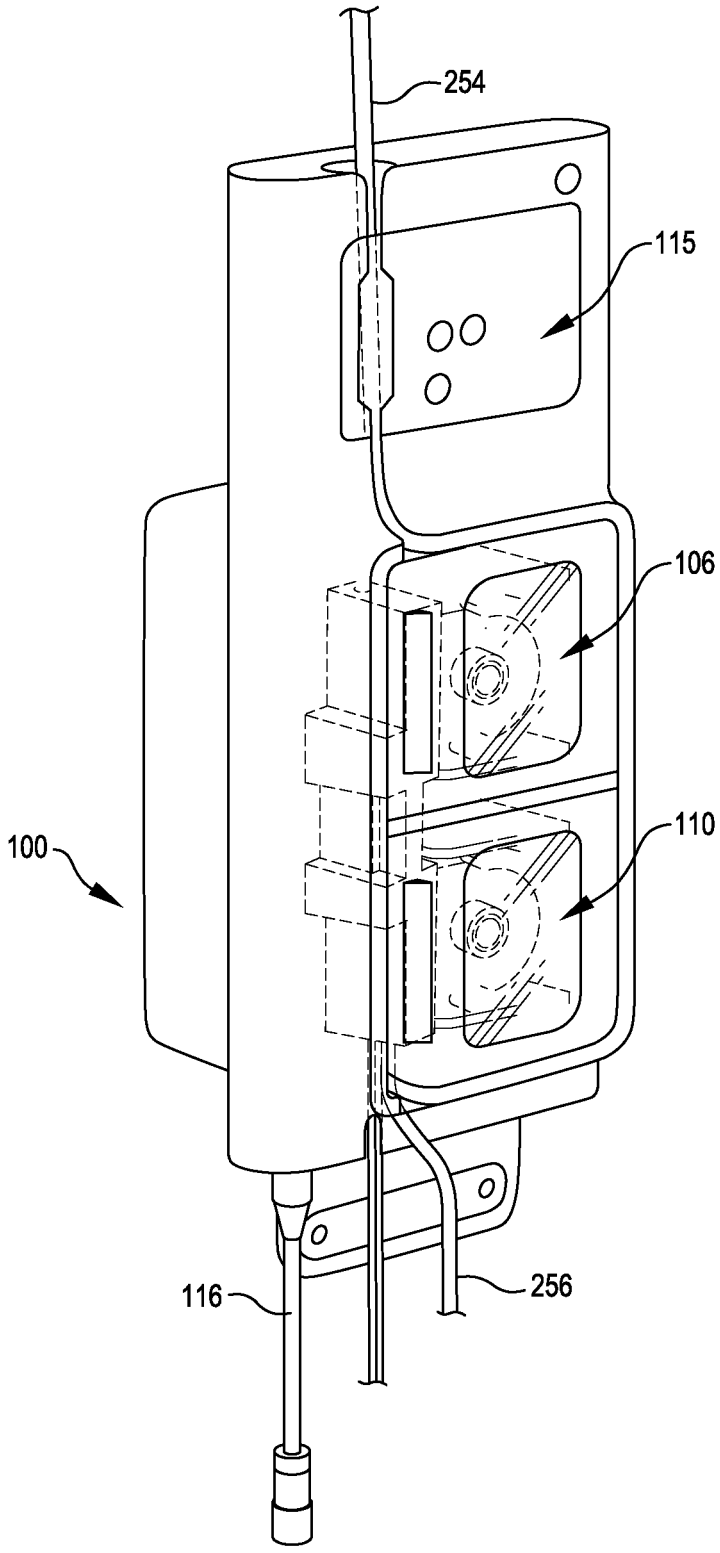


FIG. 13A

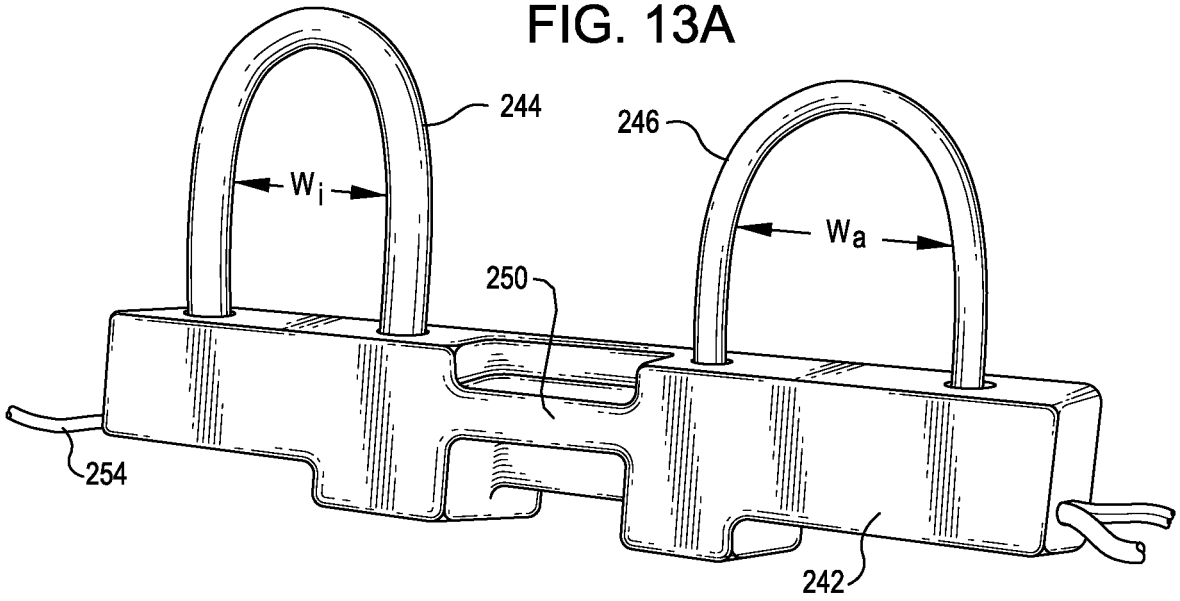


FIG. 13B

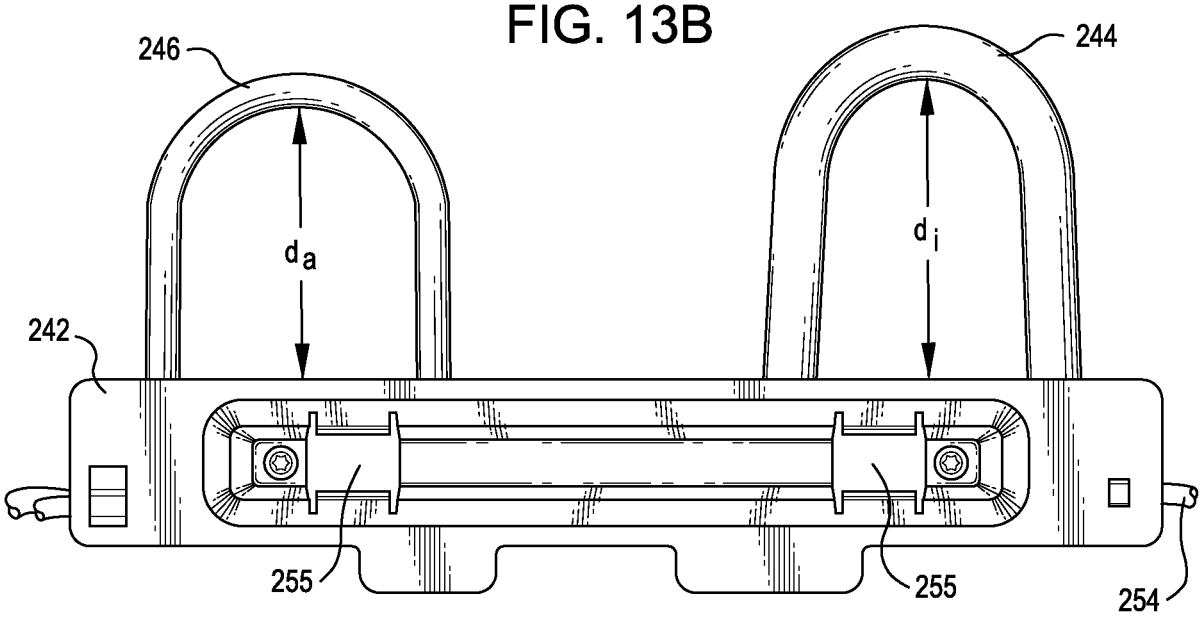


FIG. 13C

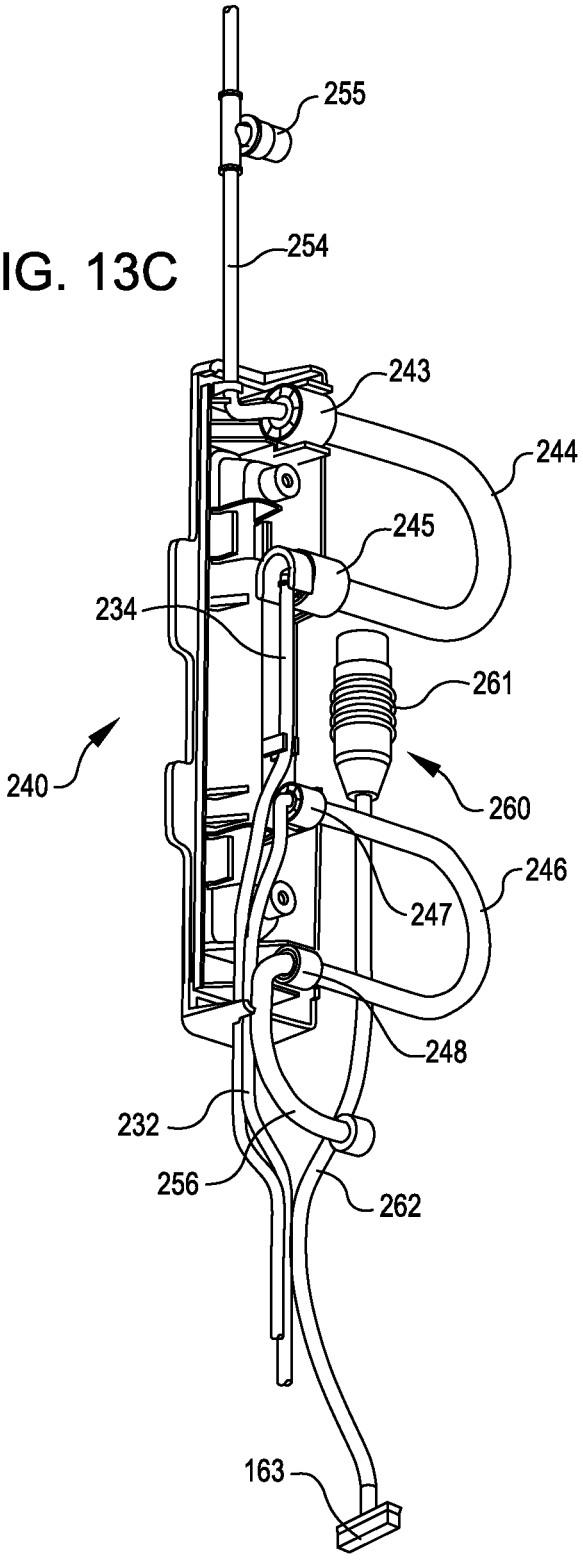


FIG. 14

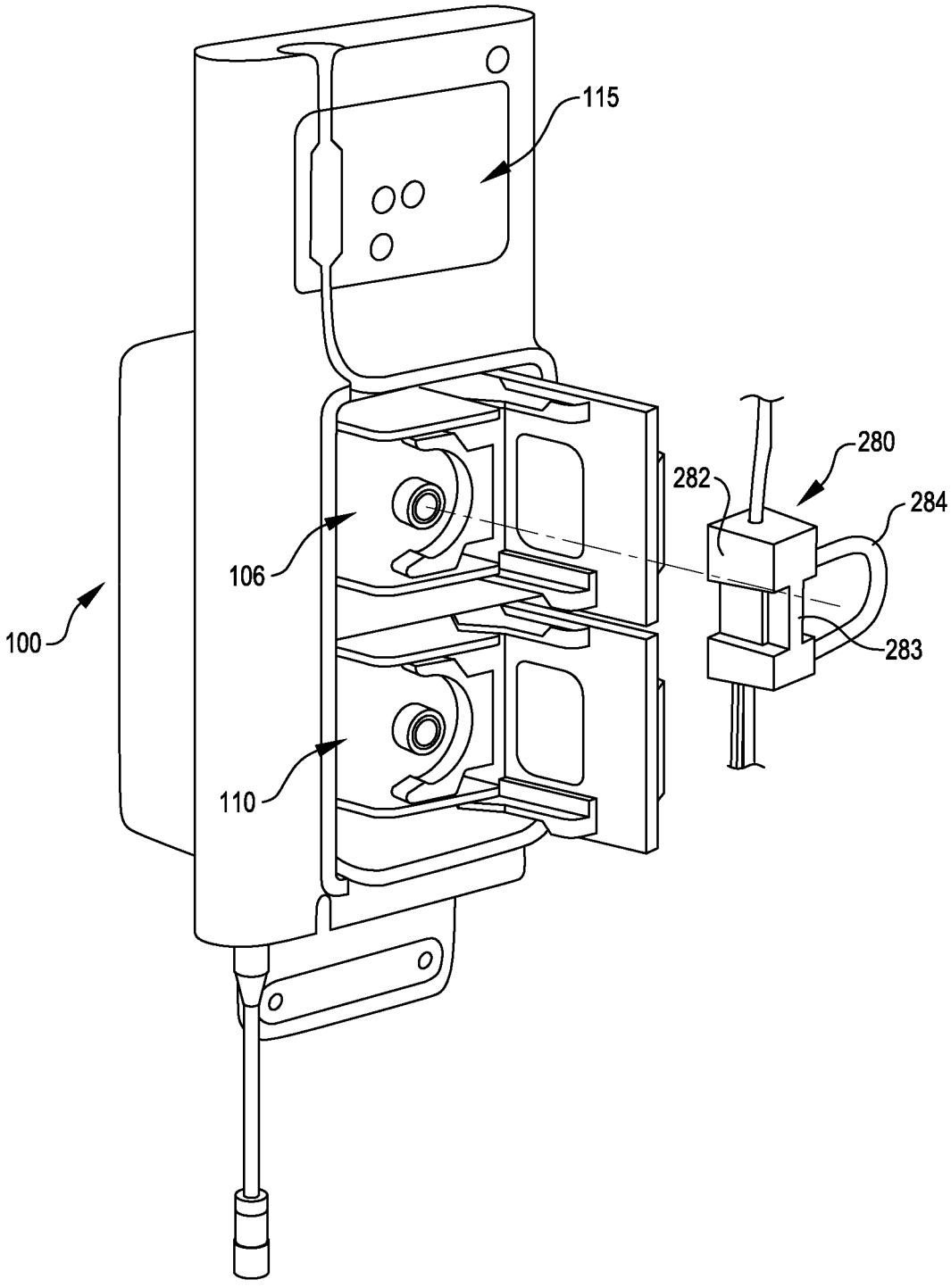


FIG. 15A

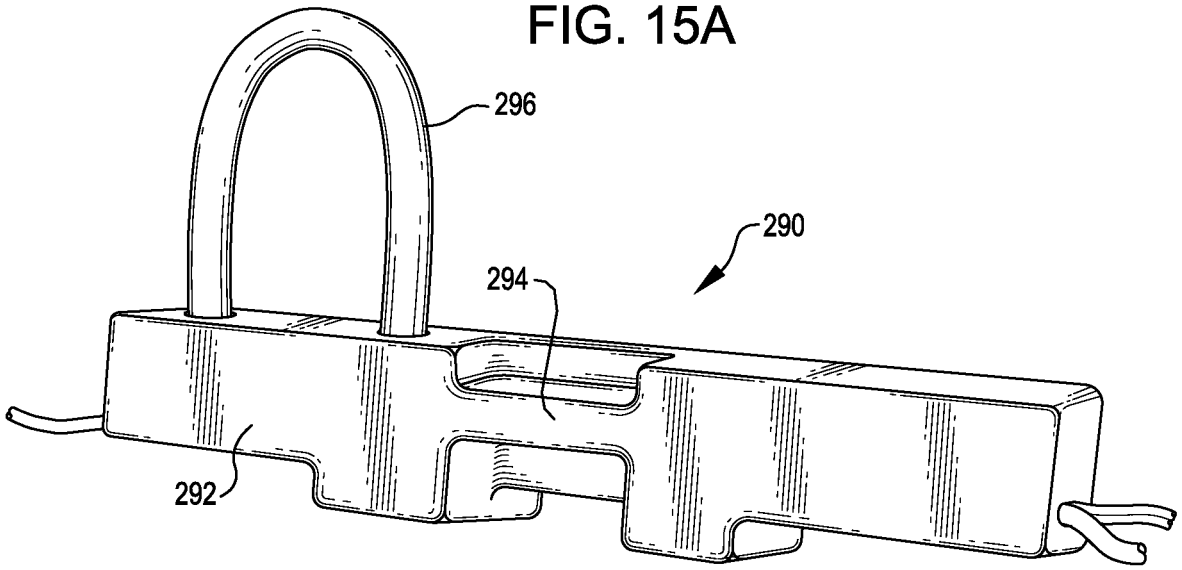
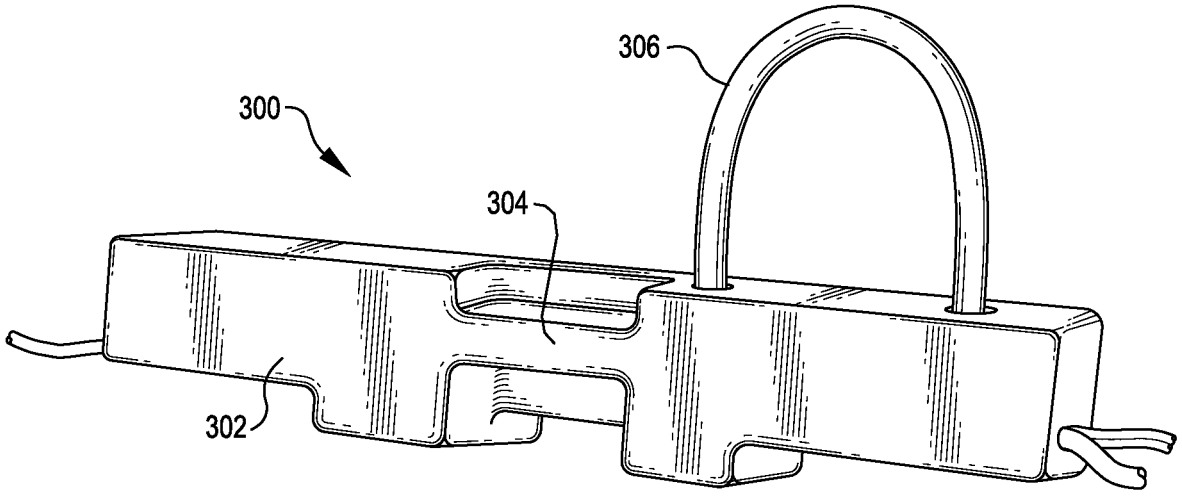


FIG. 15B



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/044279

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - F04B 43/12 (2011.01)
USPC - 417/477.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - F04B 43/12 (2011.01)
USPC - 417/53, 476, 477.1, 477.11

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0129944 A1 (STEMPLE et al) 21 May 2009 (21.05.2009) entire document	1, 4-18
Y	US 2007/0243088 A1 (NORTH) 18 October 2007 (18.10.2007) entire document	1, 4-18
Y	US 4,256,442 A (LAMADRID et al) 17 March 1981 (17.03.1981) entire document	4-5, 7-8, 11
Y	US 5,181,842 A (SUNDERLAND et al) 26 January 1993 (26.01.1993) entire document	12
Y	US 6,494,693 B1 (SUNDÉN) 17 December 2002 (17.12.2002) entire document	15
Y	WO 2008/042987 A2 (TORRANCE et al) 10 April 2008 (10.04.2008) entire document	18
A	US 5,928,177 A (BRUGGER et al) 27 July 1999 (27.07.1999) Col. 8, Lns. 55-64	2-3

☐ Further documents are listed in the continuation of Box C. ☐

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

Date of the actual completion of the international search	Date of mailing of the international search report
08 December 2011	22 DEC 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/044279

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.