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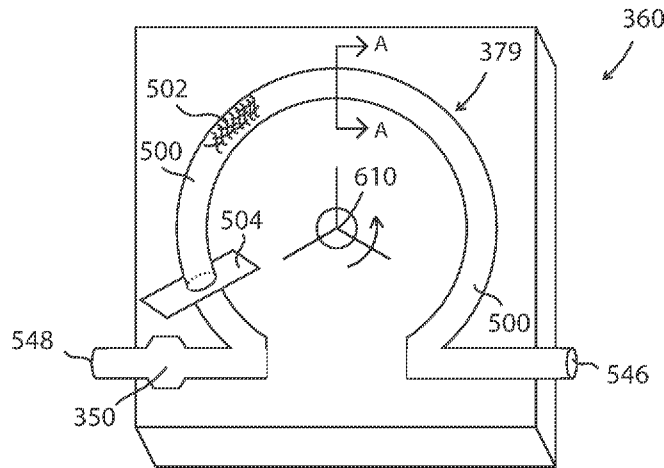


Fig. 9

(57) Abstract: An aspiration pump with controllable suction lift for aspiration of fluid and tissue from a body cavity through a surgical probe comprising a fluid conduit with collapsible walls portion of a fluid path between a pump in-port and out-port, a pump head portion to produce localized travelling occlusions at said fluid path to generate travelling fluid conduit fillable with fluid and tissue displacing from said in-port to said out-port, a vacuum lift adjustment chamber providing a sealed volume around said collapsible wall said sealed volume set to a pressure level lower than atmospheric pressure, a pump head actuator portion to operate said peristaltic pump head to displace said localized occlusions in sequence along a length of said fluid conduit between the in-port and out-port, whereby the suction lift of the aspiration pump is controlled by the pressure level at the sealed volume inside the vacuum lift adjustment chamber.



Aspiration pump with controllable suction lift

TECHNICAL FIELD:

The devices, systems, and methods disclosed herein relate generally to eye surgery and more particularly to cataract and vitreous surgery.

BACKGROUND:

The human eye functions to provide vision by transmitting light through a clear outer portion called the cornea and focusing the image by way of a crystalline lens onto a retina. The quality of the focused image depends on many factors including the size and shape of the eye, and the transparency of the cornea and the lens. When age or disease causes the lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is medically known as a cataract. An accepted treatment for this condition is surgical removal of the lens and replacement of the lens function by an artificial intraocular lens (IOL). In the United States, the majority of cataractous lenses are removed by a surgical technique called phacoemulsification. A typical surgical handpiece used for phacoemulsification procedures includes of an ultrasonically driven cutting needle surrounded by an irrigating sleeve and is attached to an electronic control surgical system. The handpiece is attached to the control surgical system by an electric cable and flexible conduit. Through the electric cable, the surgical system varies the power level transmitted by the handpiece to the attached cutting needle. The flexible conduit supplies irrigation fluid to the surgical site and draws aspiration fluid from the eye through the handpiece assembly. During

the phacoemulsification procedure, the tip of the cutting needle and the end of the irrigation sleeve are inserted into the anterior segment of the eye through a small incision in the outer tissue of the eye. The surgeon brings the tip of the cutting needle into contact with the lens of the eye, and the vibrating tip fragments the lens. The resulting fragments are aspirated out of the eye through the interior bore of the cutting needle and transported to a drain reservoir. A common complication during the phacoemulsification process arises from a blockage or occlusion of the aspirating needle. As the irrigation fluid and emulsified tissue are aspirated away from the interior of the eye through the hollow cutting needle, fragments or tissue that are larger than the diameter of the needle's bore may become clogged in the needle's tip. While the tip is clogged, vacuum pressure builds up within the aspiration conduit, including lumen of the cutting needle. Once the occlusion is cleared, a surge of fluid is removed from the eye due to a vacuum formed within the aspiration conduit. The resulting drop in pressure in the anterior chamber in the eye when the occlusion is removed is known as post-occlusion surge. This post-occlusion surge can, in some cases, cause a relatively large quantity of fluid and tissue to be aspirated out of the eye too quickly, potentially causing the eye to collapse and/or causing the lens capsule to be torn. In order to prevent the eye to collapse it has been proposed to position the aspiration pump at the surgical handpiece. This roach requires small footprint for the aspiration pump and aspiration sensors for vacuum control.

SUMMARY:

The present disclosure relates generally to devices, systems, and methods for pumping an aspiration fluid from a surgical site during an ophthalmic procedure using an aspiration pump with controllable suction lift 312 integrated with a phacoemulsification handpiece or alternatively, with other aspiration systems used in eye surgery such as irrigation/aspiration handpieces and vitrectomy handpieces.

Exemplary systems are provided herein. An exemplary phacoemulsification system may include a hand-graspable body 112 and a phacoemulsification needle 324 extending from a distal portion of the body. The phacoemulsification needle may be arranged to ultrasonically vibrate to treat an ocular condition. The phacoemulsification system may also include an ultrasonic vibration generator 320 cooperatively coupled to and arranged to vibrate the phacoemulsification needle. The phacoemulsification needle may be made to ultrasonically vibrate in response to a vibration of the ultrasonic vibration generator. The pump with controllable suction lift 312 may be carried by the hand graspable body 112 and may be configured to convey an aspiration fluid from a surgical site. The pump with controllable suction lift 312 may include a peristaltic pump head 377, an aspiration pump motor 344 and a peristaltic conduit portion 379 attached to and acted upon by the peristaltic pump head 377 rotatably driven by the aspiration pump motor 344. A peristaltic conduit portion 379 can have peristaltic pump conduit walls 500 that include flexible inelastic portions 502. The pump with controllable suction lift 312 can have a vacuum lift adjustment chamber 508 hermetically sealed around the flexible inelastic portions 502 of the peristaltic conduit wall 500 of the peristaltic conduit portion 379. The peristaltic pump head 377 can have peristaltic pump head rollers 510 or otherwise extensions that can travel over the flexible inelastic portions 502 of the peristaltic conduit wall 500 and along the path of the peristaltic conduit portion 379 collapsing into occlusion the conduit portion at a contact region. The peristaltic pump head rollers 510 can fluidically collapse the peristaltic conduit portion 379 in transverse regions along the path of the peristaltic conduit portion 379 in the form of travelling occlusions spaced by portions of conduit that can be expanded up to a maximum cross section. The expanded portions of conduit 379 can transport liquid and tissue fragments from the surgical site. The flexible inelastic portions 502 of the peristaltic conduit portion 379 allow for stable maximum cross section dimensions 504 of peristaltic conduit portion 379. Best performance is achieved when the maximum cross section dimensions 504 of the fully expanded peristaltic conduit 379 remain significantly stable within an operating pressure range between 0 and +1

atm of pressure difference from in the inside of peristaltic conduit 379. The flexible and inelastic portions 502 of wall 500 can be compounded using a mixture of impermeable, flexible and non-distensible materials first, to allow total collapse by the action of peristaltic pump head rollers 510 from the peristaltic pump head 377 and second, to allow a complete expansion with a minimum internal positive pressure up to but not beyond the maximum cross section dimensions 504 of the peristaltic conduit portion 379 up to +1 atm of conduit internal pressure. Once the maximum cross section dimensions 504 of the peristaltic conduit portion 379 has been reached, further increases in the internal positive pressure do not significantly vary the maximum cross section dimensions 504 within the operating pressure range of the aspiration pump 312. The impermeable, flexible and non-distensible materials for portions 502 can be extracted from the group of elastomers such as silicone rubber in combination with flexible minimally elastic fibers such as carbon fibers, aramid fibers or other thin flexible resistant inelastic fibers. These fibers can be weaved or otherwise disposed to produce a conduit 379 that is impermeable while having easily collapsible walls that do not expand beyond a maximum cross section when internal pressure remains below +1 atm. The peristaltic conduit portion 379 is designed to perform with high compliance below the maximum cross section dimensions 504 and to perform with near zero compliance above the maximum cross section dimensions 504 in the operating pressure range of the aspiration pump 312. A vacuum lift adjustment pressure 520 inside the vacuum lift adjustment chamber 508 can be provided by a primary vacuum source 522 controlled by a fluidics subsystem 110 to set the lift of the pump with controllable suction lift 312 through a lift adjustment module 564. The pressure value of the vacuum lift adjustment pressure 520 can be varied to effectively change the lift of pump 312. The lift of pump 312 corresponds to the maximum vacuum level achievable during operation, also known as vacuum limit. Lift of the adjustable vacuum lift aspiration pump 312 is a function of the pressure inside the vacuum lift adjustment chamber 508. The function that governs the lift of the pump with controllable suction lift 312 (P_{Lift}) with respect to the pressure inside the vacuum

lift adjustment chamber 508 (P_{Adj}) is typically $P_{Lift} = f(P_{Adj})$ where $P_{Lift} = P_{adj} + k$. The value k is determined by construction specifications. Other transfer functions can be determined depending on design. The aspiration pump 312 can discharge the aspirate fluid exiting a pump output port 548 into a waste fluid reservoir 526. The peristaltic conduit portion 379 of aspiration pump 312 may be arranged in a way that fluid and emulsified lens tissue are aspirated from the surgical site through phacoemulsification needle 324. An aspiration pump assisting control module 566 also controlled by fluidics subsystem 110 can control the pressure inside a conduit 570 downstream of adjustable vacuum lift aspiration pump 312 and can operate to reduce power required by aspiration pump 312. The aspiration pump assisting subsystem 566 can incorporate a secondary vacuum source 532 operable to reduce power, size, weight and heat dissipation of aspiration pump 312, all these elements convenient for an aspiration pump incorporated into a handpiece. Aspiration pump assisting subsystem 566 can be located within a base console 102. In one embodiment the aspiration pump assisting module 566 can provide a pressure level that is lower than the atmospheric pressure in the aspiration line 570 downstream of aspiration pump 312 in the fluid path to the waste fluid reservoir 526 using a vacuum source 532. In another embodiment a vacuum lift control 564 can activate a vacuum source 522 to provide a pressure level that is lower than atmospheric pressure inside sealed chamber 508 to provide a negative pressure around fluid conduit 379. In still another embodiment a vacuum lift control 564 module provides low pressure level inside sealed chamber 508 surrounding fluid conduit 379 and can operate in combination with pump assisting module 566 that generates a negative pressure inside fluid conduit 570 downstream of fluid conduit 379.

The vacuum source controlled by aspiration pump assisting module 566 can be of any nature including peristaltic and venturi. In one embodiment vacuum source 532 provides a pressure below atmospheric pressure inside a sealed rigid compartment 588 located downstream of fluid conduit 379. A capsule opening 540 may be provided in handpiece 112 for selective access to exchangeable parts of pump 312

such as disposable capsule 360 including peristaltic conduit portion 379. Alternatively, capsule 360 may be removably attached to a receiving portion 541 in handpiece 112. Capsule 360 can also include sensor and valve components interacting with fluid conduits passing through the capsule to sense pressure or flow and to control flow in binary or proportional fashion. An input port 546 of pump with controllable suction lift 312 can be in fluid communication with needle 324. Output port 548 of pump 312 can be in fluid communication with an aspiration fitting disposed on the hand-graspable body to allow fluid communication with waste fluid reservoir 526 through a downstream fluid conduit 570. The phacoemulsification system may also include a controller unit 103. The controller unit 103 may be configured to generate pump control signals to control pump with controllable suction lift 312 based on settings determined by a user through a user interface 104. The controller unit 103 can control the operation of the pump with adjustable lift 312 through fluidics module 110 to adjust flow rate and pump lift (vacuum limit). Flow rate can be controlled by controller unit 103 adjusting the rotary speed of aspiration pump motor 344. Controller unit 103 can regulate lift by adjusting the vacuum level provided by vacuum source 522 or 532 into vacuum lift adjustment chamber 508. According to another exemplary aspect, the present disclosure is directed to a phacoemulsification system for treating an ocular condition at a surgical site. The system may include a hand-graspable body and an irrigation system carried on the hand-graspable body. The irrigation system may convey an irrigation fluid for injection from a distal end of the hand-graspable body to the surgical site. An aspiration system may be carried on the hand-graspable body and may convey an aspiration fluid into the distal end of the hand graspable body from the surgical site. The pump with controllable suction lift 312 may include a peristaltic pump head 377 driven by an aspiration pump motor 344, a peristaltic conduit portion 379 configured within a capsule 360 receivable through a receiving portion 541 or through a capsule opening 540. The peristaltic conduit portion 379 may be detachably coupled with a surgical handpiece 112 and acted upon by peristaltic pump head 377 inside vacuum lift adjustment chamber 508. Peristaltic pump

head 377 is powered by aspiration pump motor 344. Pressure inside vacuum lift adjustment chamber 508 can be adjusted to a vacuum lift adjustment pressure magnitude 520 using first vacuum source 522 that can be operated by controller unit 103 to produce a determined vacuum level through an aspiration pump lift module 564. In this way lift of the pump with controllable suction lift 312 can be adjusted to a desired level typically according to the transfer function $P_{\text{Lift}} = P_{\text{Adj}} + k$, where the value of k varies with design. Input from in-line pressure sensors may not be required in this configuration. However, one mode of operation can consist in operating vacuum source 522 to provide a high vacuum and to limit pump motor 344 operation when a vacuum limit below the high vacuum level from vacuum source 522 is sensed using a vacuum sensor 550 upstream of pump 312 inside an aspiration conduit 340. The pump with controllable suction lift 312 may be arranged to aspirate fluid and emulsified lens tissue from the surgical site. In one embodiment aspiration pump assisting module 566 is further incorporated including a secondary vacuum source 532 operating downstream of aspiration pump 312 in a way that the pressure difference between the input port 546 and the output port 548 of aspiration pump 312 can be reduced, equalized or reversed. In this way the maximum load affecting aspiration pump motor 344 can be reduced allowing for a reduction in power, size, weight and heat dissipation of aspiration pump 312. The vacuum level produced by the secondary vacuum source 532 can be set at a steady level throughout portions of a surgical procedure eventually requiring no input from inline pressure sensors. Controller unit 103 can reduce power requirements of the pump with adjustable lift 312 by controlling a vacuum level produced by secondary vacuum generator 532 from pump assisting subsystem 566 to reduce the downstream load acting on the output port 548 of the pump with adjustable lift 312. Optionally, the controller unit 103 can use signals from an upstream pressure sensor 550, a downstream pressure sensor 552 and from an aspiration pump motor load sensor 554 to adjust the pressure level setting of the aspiration pump assisting subsystem 566 to minimize the power requirements of pump 312. Controller unit 103 and aspiration pump assisting module 566 may be in communication with the

sensors and configured to generate aspiration pump assisting module 566 control signal to control secondary vacuum source 532 based on information from these sensors. As a way of example, the aspiration pump assisting subsystem 566 can receive commands from controller unit 103 that can use the pressure signal of an upstream pressure sensor 550 and/or the pressure signal of a downstream pressure sensor 552 and/or the motor load signal 554 from a motor load sensor 556. The control unit 103 can adjust the vacuum level produced by the secondary vacuum source 532 based on the signals of the sensors to maintain the load affecting aspiration pump motor 344 at low levels using a feedback loop or a more complex algorithm such as from a trained artificial intelligence system.

Phacoemulsification needle 324 extending from the distal portion of the body 112 is arranged to ultrasonically vibrate to treat the ocular condition and an ultrasonic vibration generator 320 cooperatively coupled to and arranged to vibrate the phacoemulsification needle. According to yet another exemplary aspect, the present disclosure is directed to a phacoemulsification system that may include a hand-graspable body and a phacoemulsification needle. The needle may extend from a distal portion of the body and may be arranged to ultrasonically vibrate to treat an ocular condition. An ultrasonic vibration generator may be cooperatively coupled to and arranged to vibrate the phacoemulsification needle. The phacoemulsification needle may vibrate ultrasonically in response to a vibration of the ultrasonic vibration generator. An irrigation system may be carried on the hand-graspable body. The irrigation system may include a passageway to convey an irrigation fluid for injection from a distal end of the hand-graspable body to the surgical site. A system incorporating a pump with controllable suction lift 312 may be carried complete or in part on the hand-graspable body 112. The aspiration system can consist in a single peristaltic pump 312 and may include a conduit to convey an aspiration fluid into the distal end of the hand-graspable body from the surgical site and delivered into a waste fluid reservoir 526 through a fluid conduit. Alternatively, the aspiration system can further incorporate an extension of said fluid conduit fluidically connected with a secondary vacuum

source 532 downstream of the distal end of the hand-graspable body 112 in a base housing 102.

Secondary vacuum source 532 cooperates to reduce the power requirements of the portion of the aspiration system carried on the hand-graspable body 112. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory in nature and are intended to provide an understanding of the present disclosure without limiting the scope of the present disclosure. In that regard, additional aspects, features, and advantages of the present disclosure will be apparent to one skilled in the art from the accompanying drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS:

The accompanying drawings illustrate implementations of the devices and methods disclosed herein and together with the description explain the principles of the present disclosure.

FIG. 1 illustrates an exemplary surgical system.

FIG. 2 is an illustration of an exemplary block diagram of the surgical system of FIG. 1.

FIG. 3 is an illustration of a cross-sectional side view of an exemplary surgical instrument.

FIG. 4 is a schematic illustration of one configuration of the surgical instrument from FIG.3.

FIG. 5 is an illustration of a cross-sectional side view of another embodiment of an exemplary surgical instrument.

FIG. 6 is a schematic illustration of one configuration of the surgical instrument from FIG.5.

FIG. 7 is a schematic illustration of another configuration of the surgical instrument from FIG.5

FIG. 8 is a schematic illustration of another configuration of the surgical instruments from FIG. 3 and FIG.5

FIG. 9 is an illustration of an exemplary capsule including a peristaltic pump conduit.

FIG. 10 is a cross sectional view through a line A-A of the peristaltic pump conduit from FIG. 9 in a fully expanded configuration

FIG. 11 is a cross sectional view through a line A-A of the peristaltic pump conduit from FIG. 9 in a fully collapsed configuration as when compressed by a passing peristaltic pump roller.

FIG. 12 is a cross sectional view through a line A-A of the peristaltic pump conduit from FIG. 9 in a fully obliterated configuration caused by a passing peristaltic pump roller.

FIG. 13 is a cross sectional view through a line A-A of an alternative embodiment of the peristaltic pump conduit from FIG. 9 in a fully expanded condition.

FIG. 14 is a cross sectional view through a line A-A of an alternative embodiment of the peristaltic pump conduit from FIG. 9 in a fully obliterated configuration caused by a passing peristaltic pump roller.

FIG 15 is a perspective view of a peristaltic pump conduit built from fusion of 2 opposing sheets of flexible non-elastic material.

FIG 16 is a cross sectional view of the conduit from FIG 15 in a totally expanded condition.

FIG 17 is a cross sectional view of the conduit from FIG 15 in a totally collapsed condition.

FIG 18 is a side view of one embodiment of peristaltic pump using an inelastic peristaltic conduit and a pump roller head having rollers with springs to compensate for the variations in roller shaft radial tension due to the lack of elongation of the conduit during one circumference of pump head rotation.

FIG 19 is a cross sectional view along line D-D from FIG 18 showing total collapse of the conduit region where the pump rollers travel and compress.

FIG 20 illustrates an expanded side view of one embodiment of a pump with controllable suction lift of the present invention.

FIG 21 illustrates an expanded perspective view of the pump from FIG 20.

FIG 22 illustrates a perspective view of the pump from FIG 20.

FIG 23 illustrates a detailed top view of the peristaltic conduit of the pump from FIG 20 in collapsed condition.

FIG 24 illustrates a detailed perspective view of the peristaltic conduit of the pump from FIG 20 in collapsed condition.

FIG 25 illustrates an alternative configuration having two parallel peristaltic conduits of the pump from FIG 27 in a collapsed condition.

FIG 26 illustrates the two parallel peristaltic conduits from FIG 25 in totally expanded condition.

FIG 27 illustrates an expanded perspective view of an alternative embodiment of a pump with controllable suction lift of the present invention.

FIG 28 illustrates a perspective view of the pump from FIG 27.

FIG 29 illustrates an expanded side view of the pump from FIG 27.

FIG 30 illustrates an expanded side view of the pump from FIG 27 with sectional guides A and B.

FIG 31 is a cross sectional view at line A-A of FIG 30 showing the pump roller head.

FIG 32 is a cross sectional view at line B-B of FIG 30 showing the position of the peristaltic conduit.

FIG 33 is an overlay illustration combining FIG.31 and FIG.32 to show the relationship between the peristaltic pump head and peristaltic conduit inside the sealed chamber.

FIG 34 illustrates a perspective view of an alternative embodiment of a pump with controllable suction lift of the present invention.

FIG 35 illustrates an expanded perspective view of the pump from FIG 34.

FIG 36 shows a side cross-sectional view of the capsule from FIG 34 including the peristaltic conduit.

FIG 37 is a detailed side view of shaft with the helical peristaltic head from FIG 34.

FIG 38 illustrates a lateral cross-sectional view of the pump from FIG 34 showing the relationship between the helical peristaltic head and surrounding capsule with peristaltic conduit.

FIG 39 illustrates a side view of the pump from FIG 34 with sectional guide E.

FIG.40 illustrates a cross sectional view of the capsule only at line E-E from FIG 39 to detail an expanded peristaltic conduit.

FIG 41a illustrates a cross sectional view at line E-E from FIG 39 with the peristaltic head in a position where the peristaltic conduit can expand to its maximum cross-sectional area.

FIG 41b illustrates a cross sectional view at line E-E from FIG 39 with the peristaltic head in a position compressing the peristaltic conduit.

FIG 42 illustrates a perspective view of an alternative embodiment of a pump with controllable suction lift of the present invention.

FIG 43 illustrates an expanded perspective view of the pump from FIG 42.

FIG 44a is a bottom view and 44ba is a perspective view of the peristaltic head from the pump from FIG 42.

FIG 45a is a top view and 45b is a side view of a capsule including a disc membrane from the pump from FIG 42.

FIG 46a is a top view and 46b is a side view of a disc membrane from the pump from FIG 42 including two peristaltic conduits in collapsed condition.

FIG 47a is a top view and 47b is a side view of a disc membrane from the pump from FIG 42 including two peristaltic conduits in expanded condition.

FIG 48 is an expanded perspective view of other alternative embodiment of a pump with controllable suction lift of the present invention.

FIG 49 is a bottom view of the pump from FIG 48 illustrating the location of sensor and valve components included within.

FIG 50 is a detailed cross-sectional view of the pump from FIG 48 showing the region where sensors and actuators interfaces are located relative to the peristaltic pump head.

FIG 51 is a bottom view of a capsule of the pump from FIG 48 illustrating the fluid paths that can be included within.

FIG 52 is a perspective view of a capsule of the pump from FIG 48.

FIG 53 is a schematic view of a system including the pump with controllable suction lift of the present invention from FIG.3 and FIG.4.

FIG 54 is another schematic view of a system including the pump with controllable suction lift of the present invention from FIG.5 to FIG.7.

FIG 55 is an exemplary graph illustrating a typical cross section of a peristaltic conduit with respect to the pressure difference across the peristaltic conduit deformable non-expandable walls.

FIG 56 depicts an exemplary perspective view of a pump with controllable suction lift having a magnetically coupled detachable drive and a reduction planetary gear train.

FIG 57 depicts a schematic view of a of a pump with controllable suction lift having a common aspiration tubing both for vacuum lift regulation and also for waste fluid removal using a syringe as the vacuum source.

The accompanying drawings may be better understood by reference to the following detailed description.

FIGURE LEYENDS

surgical system 100

base housing 102

controller unit 103

display screen with user interface 104

fluid source 105

footpedal subsystem 106

footpedal 108

fluidics subsystem 110

handpiece 112

ultrasonic generator subsystem 116

vitrectomy subsystem 120

vitrectomy handpiece 122

hand-graspable body 302

distal end 304

proximal end 306

ultrasonic generator assembly 308

irrigation system 310

pump with adjustable vacuum lift 312

aspiration system 319

ultrasonic vibration generator 320

horn 322

phacoemulsification needle 324

needle distal portion 326

irrigation fitting 330

an irrigation tube 332

irrigation passage 334

irrigation sleeve 336

sleeve tip 337

aspiration conduit 340

aspiration pump motor 344

exit conduit 345

aspiration fitting 346

dual-function fitting 347

flow tube 348

reflux chamber 350

capsule 360

capsule housing 362

seal (o-ring) 363 DUP

housing 363 DUP

cartridge chamber 364

locking tabs 365

membrane 366

lift adjustment fitting 374

pressure conduit 375

peristaltic pump head 377

peristaltic conduit portion 379

needle proximal portion 392

peristaltic pump conduit walls 500

peristaltic conduit channel 501

flexible inelastic portions 502

maximum cross section dimensions 504

impermeable flexible non-distensible materials 506

vacuum lift adjustment chamber 508

vacuum port 509

peristaltic pump head rollers 510

pump head roller shaft 511

roller spring 514

vacuum lift adjustment pressure 520

first vacuum source 522

first vacuum source pressure sensor 524

lift pressure tubing 525

waste fluid reservoir 526

waste bag air exit port 527

pump motor shaft 528

seal 529

aspiration pump assisting module 530 XXX dup

second vacuum source 532

sealed rigid compartment 534

fluid level detector 536

cartridge opening 540

disposable cartridge 542

peristaltic conduit substrate 544

peristaltic conduit substrate 545

input port 546

guide 547

output port 548

conduit base 549

upstream pressure sensor 550

upstream pressure sensor signal 551

downstream pressure sensor 552

aspiration pump motor load sensor 554

motor load sensor DUP 556

irrigation control module 562

seal 563

vacuum lift control module 564

pump assist control module 566

aspiration tubing 570

irrigation tubing 572

venting valve signal 573

irrigation valve 574

venting valve signal 575

irrigation sensor 576

motor control signal 578

irrigation valve control signal 580

irrigation sensor signal 582

ultrasound power signal 584

pressure port 585

transfer pump 586

transfer tube 587

sealed rigid container 588

motor chamber 590

console pump port 592

evacuation tube 594

evacuation pump 596

waste fluid chamber 598

pump roller head axix 610

fluid level detector 650

vacuum port 652

vacuum pressure sensor 654

aspiration chamber 656

waste transfer pump 658

waste transfer conduit 660

1001 magnetic drive

1002 pump motor

1004 driving magnets

1006 pump head

1008 driven magnets

1010 pump head shaft

1012 pump gear

1014 crown gear

1016 gear train

1020 aspirating syringe

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the implementations illustrated in the drawings. Specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is intended. Any alterations and further modifications to the described devices, systems, methods, and any further application of the principles of the present disclosure are fully contemplated as would normally occur to one skilled in the art to which the disclosure relates. It is fully contemplated that the features, components, and/or steps described with respect to one implementation may be combined with the features, components, and/or steps described with respect to other implementations of the present disclosure. For example, although explanatory references are made to “ophthalmic applications,” other medical applications are included within the scope of the present disclosure. For simplicity, in some instances the same reference numbers are used throughout the drawings to refer to the same or like parts. The present disclosure relates generally to devices, systems, and methods for pumping an aspiration fluid and tissue, such as lens fragments, from a surgical site during a phacoemulsification procedure. In some implementations, the devices, systems, and methods employ a pump with controllable suction lift integrated with a phacoemulsification handpiece. With the pump disposed on the handpiece, the devices, systems, and methods may provide responsive control of the aspiration fluid flow, minimizing occlusion surge and providing a consistent fluid flow. In some implementations the pump with adjustable lift can perform with advantage when operating in cooperation with a complementary pumping element located away from the handpiece, typically on a base console. The pump with controllable suction lift may provide several advantages over alternative pumps usable in a phacoemulsification system. For example, a pump with controllable suction lift can build vacuum precisely up to a user determined limit without the absolute need of an aspiration line pressure sensor. This has a positive impact in the cost per procedure as the pressure sensor assembly and associated transducers is an expensive portion of the consumables and of the surgical console. Also, the vacuum

limit of the pump with controllable suction lift can be precisely modified during use by modification of a vacuum lift adjustment pressure that is based on a physical principle, without the need of sensors, complex algorithms or electronics. Also, a pump with controllable suction lift can operate up to high vacuum lift values when compared to flexible impeller pumps, that have reduced vacuum lift capacity. Also, a pump with controllable suction lift can operate with very low power requirements compared to conventional peristaltic and flexible impeller pumps as no power is wasted in deforming the thick elastic tubing of a conventional peristaltic pump, or in compressing the elastic impeller vanes along the narrow portion in the pump cavity of flexible impeller pumps. This feature allows to design smaller and lighter handpieces as power, weight and heat dissipation of the pump can be reduced without reducing pump capacity. In some embodiments, a pump with controllable suction lift can incorporate a handpiece pump pressure difference reduction feature or pressure inversion feature that can further reduce power consumption by reducing load working in combination with an assisting vacuum provided from a base station. The peristaltic conduit of a pump with controllable suction lift can deform or comply to lens fragments or other debris without affecting the operability of the pump and without damaging the pump. This may increase the life of the pump, as well as the effectiveness of the pump during a surgical procedure. Also, a pump with controllable suction lift may be self-priming. This may provide efficiencies in the operating room because healthcare providers would not need to prime the pump prior to performing the surgery. In addition, the pump with controllable suction lift may be reversible. Accordingly, if needed, the pump with controllable suction lift may operate in reverse to reflux and in this way dislodge tissue fragments unwantedly aspirated by the phacoemulsification needle tip.

FIG. 1 illustrates an exemplary emulsification surgical system, generally designated 100.

FIG. 2 is a block diagram of the surgical system 100 showing various subsystems that operate to perform an ophthalmic procedure, such as a phacoemulsification procedure. The surgical system 100 includes a base housing 102 with a control system 103, an associated display screen with user interface panel 104

showing data relating to system operation and allowing for user input, and a fluidics subsystem 110. Fluidics subsystem 110 includes an irrigation control module 562, a lift control module 564, and a pump assisting module 566. The surgical system 100 also includes at least a part of a number of subsystems that are used together to perform an emulsification surgical procedure. Some of these subsystems include components or elements that are separable from or not disposed on the surgical system 100. Other subsystems or components or elements thereof may be incorporated into the surgical system 100. For example, and with reference to FIG.1 and FIG.2, some example subsystems may include a foot-pedal subsystem 106 that includes, for example, a foot-pedal 108, a handpiece 112 with an integrated aspiration pump with controllable suction lift 312, an ultrasonic generator subsystem 116 that provides an ultrasonic oscillation to a cutting needle of the handpiece 112, and a vitrectomy cutter subsystem 120 including a vitrectomy handpiece 122. The handpiece 112 is fluidly coupled to fluidics subsystem 110. Irrigation module 562 receives fluid from a fluidly coupled fluid source 105 and provides irrigation fluid to handpiece 112 through fluidics subsystem 110. The handpiece 112 is also fluidly coupled through fluidics subsystem 110 to a waste fluid reservoir 526 to receive exhaust fluid and tissue fragments from a surgical site.

Now incorporating FIG. 3 and FIG. 4 fluid source 105 provides an irrigation fluid through an irrigation conduit 572 into an irrigation fitting 330. Irrigation conduit 572 can receive an irrigation pressure sensor 576 providing an irrigation pressure signal through sensor signal means 582 such as an electric cable, radio wave or other, to irrigation module 562. Irrigation conduit 572 can also pass through an irrigation valve 574 controlled by an irrigation valve control signal through a signal cable 580 from irrigation module 562. Alternatively, the fluid source 105 may be directly connected into an irrigation fitting 330 in handpiece 112 to provide irrigation fluid. An ultrasound power signal 584 connects ultrasonic generator subsystem 116 with ultrasonic vibration generator 320.

Pump assisting module 566 from fluidics subsystem 110 controls a vacuum source 532 with a vacuum sensor 552 that receives a fluid conduit from aspiration fitting 347 via conduit 570. A waste fluid reservoir 526 fluidly coupled to the output of pump 532 is disposed to receive fluid aspirated by aspiration pump 312. One or more of the subsystems may overlap and cooperate to perform various aspects of the procedure.

DESCRIPTION OF A FIRST EMBODIMENT:

The handpiece 112 seen in cross section in FIG.3 may be arranged to perform a phacoemulsification procedure at a surgical site, such as a patient's eye. The handpiece 112 is sized to be grasped and manipulated by a user. The handpiece comprises a graspable body 302, a distal end 304, and a proximal end 306. Within or carried by the graspable body 302, the handpiece 112 also includes ultrasonic generator assembly 308, an irrigation system 310, and an aspiration system 319. The ultrasonic generator assembly 308 may include an ultrasonic vibration generator 320, a horn 322, and a phacoemulsification needle 324. The ultrasonic vibration generator 320 may include a piezoelectric transducer, such as one or more piezoelectric crystals, or other components configured to generate ultrasonic vibration. In some implementations, the ultrasonic vibration generator 320 is in direct contact with the horn 322 and, when activated, may ultrasonically vibrate the horn 322. Similarly, the phacoemulsification needle 324 may be in direct contact with and carried by the horn 322 and may be threaded in position from its proximal portion 392. The physical structure of the horn 322 may be arranged to transmit or otherwise convey ultrasonic vibration from the ultrasonic vibration generator 320 to the phacoemulsification needle 324. Other forms of lens disrupting energy besides ultrasonic power can be used such as LASER power or others. As shown in FIG. 3, the phacoemulsification needle 324 is disposed at the distal end 304 of the handpiece 112. A distal portion 326 of the

phacoemulsification needle 324 forms a distal most tip of the handpiece 112, and is configured to emulsify tissue, such as a natural lens in a patient's eye, during a phacoemulsification procedure. The irrigation system 310 provides irrigation fluid to the surgical site. The irrigation system 310 may include, for example, an irrigation fitting 330, an irrigation tube 332 connected to and extending from the fluidics fitting 330, an irrigation passage 334 formed or disposed within the body 302, and an irrigation sleeve 324. Irrigation fitting 330 may be a connector arranged to couple the irrigation system 310 to a fluid conduit connected to the fluidics subsystem 110 (shown in FIG. 2) at the surgical system 100. In some implementations, the fluidics fitting 330 is a quick-disconnect fitting that allows a user to readily connect and disconnect the handpiece 112 from the fluidics subsystem 110. In some implementations, the irrigation fitting 330 is a Luer fitting. Other implementations use other types of fittings. The irrigation tube 332 extends from the fluidics fitting 330 into the graspable body 302 and fluidically connects the irrigation passage 334 to the fluidics fitting 330. In the exemplary implementation shown, a portion of the irrigation tube 332 is disposed external of the handpiece body 302. Other implementations have an irrigation tube formed within the graspable body 302. In the exemplary implementation shown, the irrigation passage 334 is a cavity formed within the graspable body 302. In other implementations, the irrigation passage 334 may be formed of one or more tubes or conduits having a lumen that may be disposed within the graspable body 302. The irrigation sleeve 336 may be in fluid communication with the irrigation passage 334 and, in the implementation shown, is arranged substantially coaxially about the phacoemulsification needle 324. Irrigation fluid flowing through the irrigation passage 334 may be directed into the irrigation sleeve 336 for passage to its tip 337, which is shown adjacent the distal portion 326 of the phacoemulsification needle 324. Accordingly, as the phacoemulsification needle 324 emulsifies tissue, irrigation fluid flows out of the tip 337 of the irrigation sleeve 336 to the surgical site. In some instances, one or more openings are formed through the sidewall of the sleeve 336 near the tip 337. The openings are in addition to the distal opening formed in the sleeve 336 through which the

needle 324 extends from the sleeve 336. The openings permit irrigation fluid to exit the sleeve 336 and into the eye, for example, during a surgical procedure. The irrigation sleeve 336 may be removably attached to the graspable body 302 or may be permanently affixed to the graspable body 302. In the implementation shown, the irrigation sleeve 336 may be received over the phacoemulsification needle 324 and threaded onto the graspable body 302 to form a portion of the distal end 304 of the handpiece 112. The aspiration system 319 may include an aspiration conduit 340, a pump with controllable suction lift 312 having a pump motor 344, and an aspiration fitting 347. In the implementation shown, the aspiration conduit 340 may be defined by a lumen through the phacoemulsification needle 324 and the horn 322. The aspiration conduit 340 may convey aspiration fluid and emulsified or fragmented tissue from the surgical site to pump with controllable suction lift 312. In other implementations, the aspiration conduit 340 may be formed of an independent aspiration tube or conduit disposed adjacent to, but not defined by, the phacoemulsification needle 324 and the horn 322. In the exemplary implementation shown, an additional flow tube 348 extends from the aspiration conduit 340 in the horn 322 to the pump with controllable suction lift 312 fluidically coupling the aspiration conduit 340 to the pump with controllable suction lift 312 through input port 546. The pump with controllable suction lift 312 is arranged to create a low pressure in the aspiration conduit 340 that is a function of a vacuum lift adjustment pressure 520 inside a vacuum lift adjustment chamber 508 integral part of the pump with controllable suction lift 312. A pressure port 509 communicates lift adjustment chamber 508 with a pressure conduit 375. An exit conduit 345 receives fluid from peristaltic conduit 379. Exit conduit 345 can have a reflux chamber 350 to hold a fluid volume to use during reflux operations. Exit conduit 345 ends in an output port 548. In a preferred embodiment, pressure conduit 375 and exit conduit 345 may merge together into a single conduit before output port 348 inside handpiece 112 both connecting through port 348 to an exit fitting 347 in order to aspirate fluid and emulsified or fragmented tissue from the surgical site. The pump with controllable suction lift 312 draws fluid from the aspiration

conduit 340 and directs the fluid to the aspiration fitting 347 up to a pressure limit that is determined by the pressure level present inside chamber 508. In the implementation shown, the aspiration fitting 347 from graspable body 302 extends at an angle therefrom for connection to a fluid conduit that extends to vacuum source 532 at base housing 102 shown in FIG. 4. Like the irrigation fitting 330, the aspiration fitting 347 may be any connector arranged to fluidly connect to a fluid conduit. The aspiration fitting 347 may be selectively detachable from a fluid conduit via any type of fitting including a quick-disconnect fitting, and, in some instances, the aspiration fitting 347 may include a Luer fitting. A pump motor 344 inside a motor chamber 590 has a shaft 528 passing through a seal 529 conveying rotary power to a peristaltic pump head 377 with peristaltic pump rollers 510. A motor control signal 576 connects motor 582 with fluidics subsystem 110. Vacuum source 532 receives waste fluid through waste fluid conduit 570 and conveys the fluid into waste fluid reservoir 526. An optional upstream vacuum sensor 550 can be located in the fluid path between aspiration needle 324 and peristaltic conduit 379 input port 546 with a sensor signal transmitted to control system 103 via signal conveying means 551 such as a signal cable. Turning to FIGS. 9 to 14, the surgical aspiration system with adjustable vacuum lift of the present invention includes peristaltic conduit portion 379 having an input port 546 and an output port 548. A reflux chamber 350 can be incorporated proximal to output port 548 as an extra volume reservoir for reflux operations. The impermeable peristaltic conduit portion 379 has a wall 500 that can have regions built with rigid inelastic materials combined with other regions built with bendable non-expandable dimensionally stable fabric-like materials 502 in a design that allows total collapse of the peristaltic conduit portion 379 cross section 504 by the action of pump rollers 510 or otherwise by the action of extensions from a peristaltic pump head 377. Peristaltic conduit portion 379 can be disposed in a removably attachable capsule 360. Portions 502 from wall 500 can be compounded by an array of different materials, for example silicone rubber providing impermeability and bendability together with a mesh or weaved inelastic fibers such as aramid fibers, carbon fibers, glass fibers, or other textile fibers

with low distensibility. Different patterns of fiber arrangements can be considered. Pump roller head 377 can rotate around a pump roller head axis 610 in a way that rollers 510 rotate around shafts 511 along at least a portion of the path of peristaltic conduit 379. Shown in FIGS. 10 and 11 is a section of peristaltic conduit 379 along line A-A from FIG. 9. FIG. 10 depicts peristaltic conduit 379 fully inflated with wall 500 maximally expanded and cross section 504 at its maximum dimensions as it would occur when conduit 379 has positive internal pressure across wall 500. FIG. 11 depicts peristaltic conduit 379 completely collapsed and a cross section 504 of zero. The collapsed condition depicted in FIG 11 can occur by the action of a peristaltic pump roller 510 passing along a portion of the path of conduit 379 producing total collapse by compression between roller 510 and an underlying substrate 544 from capsule 360. Conduit 379 can also remain in a collapsed condition when the pressure difference across wall 500 is not higher on the inside of conduit 379 compared to the outside. In some embodiments conduit 379 can be designed with a low degree of elasticity enough to naturally remain in a collapsed condition when the pressure difference across wall 500 is zero as seen in FIG.11 but easily expandable to its maximum cross section when a low positive internal pressure exists. Shown in FIG.13 and FIG.14 is an alternative embodiment for capsule 360 where wall 500 from conduit 379 is composed of two distinct portions. A first portion 500a is built with a bendable non-distensible membrane 502 suitable for deformation and compression by a pump roller 510. A second portion 500b is carved in the substrate 544 of capsule 360 to form a peristaltic conduit channel 501. with a shape that conforms to the shape of a passing roller 510. Substrate 544 can be made of a rigid material such as PMMA or an elastic material such as an elastomeric substance preferably with a medium to high durometer index. FIGS. 15 to 19 illustrate an alternative embodiment for a pump with controllable suction lift 312 of the present invention. As shown in FIG.18 peristaltic head 377 has rollers 510 symmetrically disposed around shaft 528. Rollers 510 can rotate or slidably displace along a section of peristaltic conduit 379 with walls 500 made of bendable non-expandable material. A force from rollers 510 maintains a range of tension in

conduit 379 by action of springs 514. Springs 514 allow for centripetal and centrifugal displacement of rollers 510 for adjustment of variation in the chord length during rotation of head 344. Springs 314 prevent excessive tension or looseness of conduit 379 in order to maintain the peristaltic action while operating with reduced power. As an alternative, a spring supported base 549 can serve the same object without need of springs holding rollers 510 shafts. Spring 514 force is calculated to produce a tension fluctuation of conduit 379 during rotation of head 377 in a range sufficiently high to allow the peristaltic action to occur properly (i.e. without slippage) but not beyond, to avoid unnecessary loading of the pump motor 344. In this example wall 500 is composed of a flexible non-distensible material. Conduit 379 can be constructed by adhesion of two sheets of material 500c and 500d to facilitate total collapse of the cross section. In some embodiments, the collapse of cross section 504 can be enhanced by bending of conduit 379 along a main axis beyond a critical angle, typically 120 degrees, and in a short radius. FIG.18a depicts an embodiment with two low radius rollers implemented to enhance the kinking effect by bending conduit 379 beyond the kink angle of 120 degrees. This configuration promotes a conduit 379 transverse kinking effect that travels as the roller displaces under the conduit. FIG.18b has three rollers and can operate with or without a kink effect and still produce an effective peristaltic action. The configuration with two fused sheets 500c and 500d reduces leakage at the corners compared to when a single piece tubing is used. This allows to further reduce the compression force required by rollers 510 to collapse the peristaltic conduit 379 to reduce load. FIG.15 is a perspective view of a longitudinal section of conduit 379 from FIG.18b depicted in a fully expanded configuration. FIG.16 is a cross sectional view from FIG.15 showing the region where sheets 500c and 500d join at angles 500e and 500f. Angles 500e and 500f of conduit 379 facilitate conduit flattening and collapse during bending and compression by rollers 510 as they prevent fluid leakage at the margins that would otherwise require higher roller compression force over the conduit. FIG.17 is a cross sectional view illustrating a kinked region of conduit 379 due to bending beyond the critical angle with a small radius by

action of a roller 510 from FIG.18. Sheets 500c and 500d are aligned in parallel with angles 500e and 500f equaling zero at each side of conduit 379 deformed by a passing roller 510 and leaving no space for fluid leakage in the collapsed conduit region. The same effect can be produced by compression of a roller 510 of conduit 379 toward a substrate 544. Shown in FIGS.18a, 18b and FIG.19 is a peristaltic pump 312 using the peristaltic conduit 379 from FIGS.15 to 17. Conduit 379 is fixated to a base plate 549. Pump head 377 has rollers 510 engaging conduit 379. During rotation, rollers 510 produce a peristaltic action displacing fluid and tissue fragments inside conduit 379 from input 546 to output 548. Walls 500 of conduit 379 are built from bendable non-expandable materials. To prevent sharp variations in tension of conduit 379 during rotation of head 377 rollers 510 require to be capable of some radial play while maintaining a stable force into conduit 379. In the example in FIG.18b slots 512 accommodate the shafts of rollers 510 and these shafts are supported by springs 514 to apply the required radial force and at the same time prevent head 377 locking. This because the chord length around rollers 510 in the depicted configuration for conduit 379 varies with peristaltic pump head rotary 377 position. The embodiment --shown has two rollers rotating around a fixed axis, or not rotating at all but sliding along conduit 379. The spring action that compensates the variation in chord length along the path of conduit 379 during head 377 rotation has been displaced to base plate 549 supported by springs 514 and allowed to oscillate along one axis parallel to a guide 547 during head 377 rotation. FIG.19 is a sectional view through lines D-D in FIG.18b illustrating total collapse of conduit 379 in the region in contact with rollers 510.

OPERATION OF A FIRST EMBODIMENT:

Source 105 provides irrigation fluid into the surgical space typically by opening valve 574 under command of the operator interacting with the base console 102 through user interface 104 and foot-

pedal 108. Irrigation fluid follows the irrigation path and can reach the surgical site through irrigation sleeve 336 due to gravitational force or in some systems, by forced infusion. The surgical aspiration system with adjustable vacuum lift of the present invention can aspirate fluid from a surgical site at a desired flow rate and up to a predetermined vacuum limit. The operator selects a desired vacuum limit and maximum flow rate through user interface 104 and commands the system into operation by actuation on foot-pedal 108. In some implementations, the aspiration pump motor 344 may be a variable speed motor controlled by controller system 103 of the surgical system 100. In some implementations, the aspiration pump motor 344 may be reversible, and because of the bidirectional nature of operation of the pump with controllable suction lift is able to reverse flow to reflux. The reflux may be effective to clear the phacoemulsification needle from occlusions and to release tissues unwanted to become aspirated. Reflux chamber 350 contains a reserve volume for reflux operations. Responsive to pump control signals generated at the controller system 103, the aspiration pump motor 344 may increase flow, decrease flow, or maintain flow at a desired flow rate eventually based on a measured or on a calculated parameter indicative of pressure at the surgical site. Also responsive to control signals generated at the controller system 103, the fluidics module can command to increase vacuum, decrease vacuum, or maintain vacuum at a desired level eventually based on a measured or calculated parameter indicative of pressure at the surgical site. Vacuum achievable at the aspirating distal end 304 of handpiece 112 is determined by the vacuum level inside vacuum lift adjustment chamber 508 which in the embodiment from FIGS. 3 and 4 is produced by vacuum source 532 through aspiration tubing 570, exit fitting 347, pressure conduit 375 and port 509. The vacuum level produced by vacuum source 532 is a function of the vacuum limit configured by an operator through user interface 104. The vacuum is delivered into tubing 570 and is typically regulated by a feedback loop from a pressure signal provided by pressure sensor 552 through fluidics subsystem 110 and controller unit 103. Vacuum source 532 plays a dual role by first providing the vacuum level that sets the lift (or vacuum

limit) of pump 312 while at the same time producing the pressure differential that directs the waste fluid from the exit fitting 347 into the waste fluid reservoir 526. An alternative mode of operation can also be implemented when using optional vacuum sensor 550. In this mode, a fixed vacuum level can be set by vacuum source 532 inside chamber 508 that is higher than the maximum vacuum level set for aspiration through user interface 104 and processor 103. A feedback pressure signal from sensor 550 can be received by processor 103 sent through pressure signal conveying means 551 such as a cable. Processor 103 and fluidics module 110 can adjust motor 344 speed and direction to allow the vacuum level inside fluid conduit 340 upstream of pump 312 to a vacuum limit set by user interface 104 and processor 103.

ALTERNATIVE EMBODIMENT 1:

An alternative embodiment is depicted in FIG.5 and FIG.6 where vacuum lift adjustment chamber 508 is connected to a pressure source 522 located inside base housing 102 or alternatively inside handpiece 112 (not shown). Port 509 is in fluid connection with a lift adjustment fitting 374 which can connect through a lift pressure tubing 525 with pressure sensor 524 and pressure source 522. An aspiration fitting 346 receives aspiration tubing 570 directly communicating with waste fluid reservoir 526. In this embodiment the pump 312 vacuum limit is determined by the vacuum level produced by pressure source 522 and conveyed into chamber 508 through tubing 525 and port 509.

ALTERNATIVE EMBODIMENT 2:

Another alternative embodiment is depicted in FIG.7. Here vacuum lift adjustment chamber 508 is also connected to a pressure source 522 located inside base housing 102 or alternatively inside handpiece

112 (not shown). Port 509 is in fluid connection with a lift adjustment fitting 374 which can connect through a lift pressure tubing 525 with pressure sensor 524 and pressure source 522. An aspiration fitting 346 receives aspiration tubing 570 in fluid communication with aspiration assist pump 532 which directs the fluid into waste fluid reservoir 526. Processor 103, fluidics subsystem 110 and aspiration assist module 566 operate to control vacuum source 532 to produce a vacuum level that can reduce the pressure difference between pump 312 input port 546 and output port 548 by producing a pressure level inside conduit 570 that is lower than atmospheric pressure. In this way pump 312 head can be reduced to reduce pump size and power consumption by relaying part of the pumping action to a base housing 102 pump 532. The vacuum level provided inside conduit 570 by pump 532 can be fixed or regulated. In the case of a fixed vacuum inside conduit 570 this is preferably set to a high vacuum level in a way that pump 312 can operate transferring fluid from a relatively high pressure site at input port 546 to a relatively low pressure site at output port 548 for minimum power consumption. As an alternative, vacuum generated by pump 532 and transmitted into aspiration tubing 570 can be regulated to a vacuum level that can be a function of the vacuum level inside chamber 508. In one typical configuration using regulated vacuum from pump 532 the vacuum level inside tube 570 can be adjusted to follow the vacuum level inside chamber 508. In this configuration the pressure difference between the input port 546 and the output port 548 of pump 312 is reduced to a minimum during operation.

ALTERNATIVE EMBODIMENT 3:

Another alternative embodiment is depicted in FIG.8. An aspiration fitting 347 receives aspiration tubing 570 communicating with a sealed rigid container 588. Assist pump 532 can generate a vacuum level inside container 588. The vacuum level provided by pump 532 can be regulated or unregulated as

detailed for the previous embodiment. A fluid level detector 536 can command a fluid transfer pump 586 to extract waste fluid inside container 588 into waste fluid reservoir 526 when container 588 becomes too filled. Alternatively, aspiration fitting 347 can receive vacuum from a syringe, as shown in Fig.57. Shown in FIG.20 to FIG.24 is one implementation of the pump with controllable suction lift of the present invention and can operate in any of the configurations illustrated in FIG.3 to FIG.8. As seen in FIG. 20 and 21 hand graspable body 302 includes a motor 344 and a peristaltic head 377 with two rollers 510. A detachably coupled magnetic drive system 1001 can also be incorporated as depicted in FIG.56 and FIG.57 to provide complete fluidic isolation between the pump powering motor 582 and the pump mechanism 377 contained in pump head 1006 completely eliminating the need of seals such as o-ring 529. Magnetic drive system 1001 contains motor 1002 with magnets 1004 disposed around the motor shaft in a plane. In operation, driving magnets 1004 become magnetically coupled with driven magnets 1008 disposed inside pump head to magnetically receive the rotary motion from motor 1002 and transmit this rotary motion to pump head through a shaft 1010. Shaft 1010 has rotationally fixed pinion 1012 which in turn conveys rotational energy to a crown gear 1014 rotationally linked to rollers 510. Between shaft 1010 and pinion 1012 a reduction mechanism can be included such as a planetary reduction gear train 1016. Magnets 1004 and 1008 are typically arranged in alternating polarities to become magnetically attracted and rotationally locked between each other. A capsule 360 receives peristaltic conduit 379. Body 302 has a capsule housing 362 adapted to receive capsule 360 in a stable locked position through locking tabs 365 that can removable attach to complementary spaces 368 in capsule 360. Shown in FIG.22 is the assembled pump 312 with capsule 360 locked in operation position. In this situation, when head 377 rotates by action of motor 344, rollers 510 travel over and compress into a collapsed state the walls 500 of peristaltic conduit 379 producing the peristaltic action. The vacuum level present inside chamber 508 determines the lift of the pump. The pump can produce a maximum vacuum that is equal to the vacuum level inside chamber 508. Alternatively, a vacuum signal

551 provided by vacuum sensor 550 can allow processor 302 to limit the vacuum to a predetermined level by adjusting motor 344 speed according to pressure sensor 550 readings in a feedback loop. The usable range of vacuum level adjustable in this modality can only be lower than the vacuum level inside chamber 508. FIG.23 and FIG.24 are detailed views of the peristaltic conduit from FIG.20 seen in an empty or collapsed condition. FIGS. 25 and 26 illustrates an embodiment where capsule 360 from FIGS.20 to 22 holds two aspiration conduits disposed to operate in parallel. In this configuration flow rate can be increased. When the two conduits are disposed out of phase (preferably 90 degrees of offset for a two roller pump) pump ripple can be reduced. FIG.25 depicts the two conduits 379 in an empty or collapsed condition. FIG.26 depicts the conduits 379 fully inflated to the maximum cross section as illustrated in the graph for FIG.55. Shown in FIG.27 to FIG.33 is another implementation of the pump with controllable suction lift of the present invention. As seen in FIG. 27 the pump includes a motor 344 and a peristaltic head 377 with three rollers 510. A capsule 360 includes peristaltic conduit 379. Capsule 360 can be removably attached in a locked position in a way that peristaltic head 377 interacts with conduit 379 in an operable configuration. Shown in FIG.28 is the assembled pump 312 with capsule 360 locked in operation position. In this situation, when head 377 rotates by action of motor 344, rollers 510 travel over and compress into a collapsed state the walls 500 of peristaltic conduit 379 producing the peristaltic action. The vacuum level present inside chamber 508 determines the lift of the pump. The pump can operate with a maximum vacuum that is equal to the vacuum level inside chamber 508. Alternatively, a vacuum signal 551 provided by vacuum sensor 550 can allow processor 302 to limit the vacuum to a predetermined level. In this configuration the vacuum limit can only be lower than the vacuum level inside chamber 508. FIG.29 and FIG.30 are detailed side views of the peristaltic conduit from FIG.27. FIG.31 shows a cross sectional view along line A-A from FIG.30 illustrating the position of the peristaltic head 377 and three rollers 510 and its relationship with peristaltic conduit walls 500. FIG.32 is a cross section along line B-B from FIG.30 illustrating the location of the peristaltic conduit

inside capsule 360 before attaching the peristaltic pump head 377. FIG.33 is a cross section along line B-B from FIG.30 this time illustrating the relative position of the various components of the pump from FIG.27. Shown in FIG.34 to FIG.41 is another implementation of the pump with controllable suction lift 312 of the present invention. The pump includes a motor 344 and a helical peristaltic head 377 along a pump shaft 528. A capsule 360 includes peristaltic conduit 379. Capsule 360 can be removably attached in a locked position in a way that peristaltic head 377 interacts with conduit 379 in an operable configuration for peristaltic action. Shown in FIG.34 is the assembled pump 312 with capsule 360 locked in operation position. In this situation, when helical peristaltic head 377 rotates by action of motor 344 it locally compresses and travels over the walls 500 of peristaltic conduit 379 displacing collapsed regions of conduit 379 producing the peristaltic action. The vacuum level present inside chamber 508 determines the lift of the pump. The pump can operate with a maximum vacuum that is equal to the vacuum level inside chamber 508. Alternatively, a vacuum signal 551 provided by vacuum sensor 550 can allow processor 302 to limit the vacuum to a predetermined level. This vacuum level should be lower than the vacuum inside chamber 508. FIG.35 illustrates the pump from FIG.34 with capsule 360 removed from its operational position. FIG.36 to FIG.38 are detailed side views of portions of pump 312 from FIG.34 showing the relationship between the movable parts 528 and 377 with respect to the fixed parts inside capsule 360 including conduit 379. FIG.40 shows a mid-cross-sectional view of the unattached capsule 360 from FIG.36 with one fluid conduit in expanded condition. Fig 41a shows a cross-sectional view along line E-E from FIG.39 with the peristaltic head 377 away from contact with wall 500 of peristaltic conduit 379. In this configuration, peristaltic conduit 379 can expand at this section up to its maximum cross section dimensions 504 when the pressure difference between chamber 508 and conduit 379 across wall 500 is positive inside conduit 379. FIG.41b shows a cross sectional view along line E-E from FIG.38 where the helical peristaltic head 377 is sliding over wall 500 of peristaltic conduit 379. In this configuration, peristaltic conduit 379 is collapsed at this section. In this way a positive fluid

displacement occurs between input 546 and output 548 with rotation of head 377 producing spaced occlusions that travel along conduit 379 from input 546 to output 548 producing a peristaltic pumping action. If the pressure difference between chamber 508 and conduit 379 across wall 500 is not positive inside conduit 379 the conduit does not expand and flow ceases to continue between input 546 and output 548, regardless of the speed of rotation of shaft 376 and head 377. In this way the lift of the pump is limited to the vacuum level inside chamber 508. Shown in FIG.42 to FIG.47 is another implementation of the pump with controllable suction lift of the present invention. The pump includes a motor 344 and a peristaltic head 377 with rollers 510. A capsule 360 can include one or more peristaltic conduits 379 operating in parallel. Capsule 360 can be removably attached in a locked position in a way that peristaltic head 377 interacts with conduits 379 in an operable configuration for fluid transport by peristaltic effect between in port 546 and out port 548. Shown in FIG.42 is the assembled pump 312 with capsule 360 locked in operation position. In this situation, when head 377 rotates by action of motor 344, rollers 510 travel over and compress into a collapsed state the walls 500 of peristaltic conduits 379 producing the peristaltic action. The regions not compressed by rollers 510 can expand according to the pressure difference between the inside of conduit 379 and the surrounding chamber 508 across walls 500. The vacuum level present inside chamber 508 determines the lift of the pump. The pump can operate with a maximum vacuum that is about equal to the vacuum level inside chamber 508. Alternatively, a vacuum signal 551 provided by vacuum sensor 550 can allow processor 103 to limit the vacuum level only up to a predetermined level. This vacuum should be lower than the vacuum level inside chamber 508. FIG 43 illustrates pump 312 in an expanded view. Capsule 360 can include a pre-formed membrane 366 providing walls 500 to complete conduit 379 in combination with substrate 544 from capsule 360. A typical peristaltic head 377 is shown in FIG.44a and FIG.44b with rollers 510 radially disposed to operate in a planar configuration interacting with membrane 366 compressing in a collapsing manner segments of conduit 379 towards a floor in capsule 360 to produce the peristaltic

action with rotation. FIG.45a is a top view of capsule 360 showing two fluid conduits 379 disposed in parallel between input 546 and output 548 that can cooperate with peristaltic pump head 377 and rollers 510 to produce a positive displacement of fluid across pump 312. FIG.45b is a side view of capsule 360 from pump 312 in FIG.42. O-ring 563 produces an airtight seal when capsule 360 is locked in operation position with body 302 to form airtight chamber 508. Membrane 366 is illustrated in FIG.46 and FIG. 47. Membrane 366 is made of a foldable, non-elastic membrane material and can be compressed, fused, adhered or otherwise built into capsule 360. In this example, membrane 366 includes two peristaltic conduits disposed for operation in parallel with pump 312 from FIG. 42, but other numbers and arrays of peristaltic conduits can be implemented. FIG.46a shows a top view and FIG 46b shows a cross-sectional side view at line B-B from FIG.46a of membrane 366 with wall 500 in a flat occluded condition as would occur when a roller 510 is passing over, and also, as would occur when the pressure difference across wall 500 of membrane 366 becomes positive inside chamber 508 with respect to conduit 379. FIG.47a shows a top view and FIG 47b shows a cross-sectional side view at line C-C from FIG.47a of membrane 366 with wall 500 in a fully expanded condition as would occur when no roller 510 is passing over conduit 379 and the pressure difference across wall 500 of membrane 366 is positive inside conduit 379 with respect to chamber 508. The arrangement in parallel of two or more conduits 379 can allow for increased volume transfer per unit time (flow) and can also allow to reduce pressure and volume fluctuations during pump operation if arranged with a relative offset regarding rollers 510 from peristaltic head 377. In the illustrated example of two conduits 379 and an odd number of equally spaced rollers 510, an offset of 180 degrees is optimal for ripple cancellation. Shown in FIG.48 to 52 is another embodiment for pump 312 further incorporating sensors and actuators typical of phacoemulsification consoles to control operation of the pump that could be otherwise located in a cassette at base housing 102. The hand-graspable body 302 including pump 312 from FIG.48 has a pump housing 303 home to motor 344. Capsule 360 can incorporate irrigation fitting 330 in fluid

communication with irrigation tube 332. The fluid conduit between fitting 330 and tube 332 can have attached an irrigation valve 574 and an irrigation pressure sensor 576. Irrigation valve 574 has an actuator portion 574a located inside housing 303 and a membrane portion 574b located at capsule 360. Valve membrane portion 574b can be actuated upon by actuator portion 574a to open and close valve 574 to allow or block irrigation flow. Valve actuator portion 574a can be of electromagnetic nature, piezo electric nature, pneumatic nature or any other actuator suitable for operating a membrane-based valve. Valve 574 can operate in an absolute or proportional mode. Irrigation pressure sensor 576 has a transducer portion 576a and a membrane portion 576b disposed in similar fashion as valve 574 portions a and b. A pressure level inside the fluid conduit between fitting 330 and tube 332 can be sensed across membrane 576b measuring a force using transducer portion 576a to provide a signal proportional to irrigation pressure fed into fluidics subsystem 110 and processor 103. The fluid conduit between input port 546 and output port 548 can include a venting valve 575 and upstream pressure sensor 550. Lift adjustment fitting 374 is in fluid communication with sealed chamber 508. Venting valve 575 has an actuator portion 575a and a membrane portion 575b that can be normally actuated upon by actuator portion 575a to maintain valve 575 in a normally-closed condition. When a venting operation is required, controller 103 can command valve actuator 575a to remove an actuation force from membrane portion 575b to allow flow between the irrigation conduit from fitting 330 and input port 546. Upstream pressure sensor 550 has a transducer portion 550a and a membrane portion 550b. Pressure in the fluid conduit between input port 546 and fluid conduit 379 can be transmitted across membrane 550b exerting a force onto transducer portion 550a to provide a signal proportional to an aspiration pressure in aspiration conduit 340 fed into processor 103. Venting valve 575 and upstream pressure sensor 550 are arranged in similar fashion as irrigation pressure sensor 576 portions a and b, and irrigation valve 574 portions a and b. Shown in FIG.49 is an axial view of graspable body 302 illustrating the location of the various sensor and actuator interfaces disposed within. Fig.50 further

illustrates the relative position of the sensors and actuators regarding peristaltic head 377 with rollers 510. A single membrane 366 can include portions dedicated to conduits 379, sensor portions 550b and 576b, and valves 574b and 575b. Alternatively, the peristaltic conduit 379, sensors 550b and 576b, and valves 574b and 575b can be built using separated segments of membrane 366. FIG. 51 is an illustration of the diverse conduits integrated into capsule 360 for pump operation. As seen in FIG.52 capsule 360 provides the substrate for conduit 379 as well as the membrane portions of valve and sensor elements 574b, 575b, 550b and 576b attached to their respective fluid conduits. Shown in FIG.53 is a schematic illustration of the embodiment depicted in FIG.3 and FIG.4 further incorporating irrigation and aspiration pressure sensors 576, 550 as well as irrigation and venting valves 574, 575. Shown in FIG.54 is a schematic illustration of the embodiments depicted in FIG.5 to FIG.8 further incorporating irrigation and aspiration pressure sensors 576, 550 as well as irrigation and venting valves 574, 575. FIG.55 is an exemplary graph of the cross-sectional area of a typical peristaltic fluid conduit portion 379 of the present invention. As illustrated in this graph, peristaltic fluid conduit 379 has at least in part, thin, foldable, inelastic walls 500 that allow the conduit to inflate with minimal internal pressure up to its maximum capacity. The inelastic properties of walls 500 limit the cross-sectional area 504 from further expanding with further increments in conduit 379 internal pressure at least up to 1 atm. The properties of the thin, foldable, inelastic walls 500 of conduit 379 can be obtained by a combination of weaved or meshed fibers impermeabilized by impregnation with elastomeric substances. As an alternative, a thin walled elastomeric tubing surrounded by and eventually adhered to a precisely fitted non-elastic fabric sheath can also be used. Other conduit wall designs can be implemented without departing from the scope of the present invention. In some implementations, the aspiration pump motor 344 comprises a shaft that directly drives the peristaltic pump head 377. In other implementations, the aspiration pump motor 344 drives a transmission or gear train that drives the peristaltic pump head 377. In the exemplary implementation shown, the aspiration pump motor 344 is disposed within the graspable

body 112. Other implementations include the aspiration pump motor 344 external of graspable body 112, or otherwise carried by graspable body 112. Consistent with this, in some implementations, the handpiece 112 may include an upstream pressure sensor 550 associated with the fluidics subsystem 110. In some exemplary implementations, the upstream pressure sensor 550 may be located along the aspiration conduit 340 or located near the distal end 304 and sensible to occlusions that interfere the fluid communication with the surgical site. In some implementations, the upstream pressure sensor 550 may be located within the surgical site and in communication with a controller 103 having a fluidics subsystem 110. In some implementations, the upstream pressure sensor 550 detects a pressure at the surgical site or a pressure associated with the surgical site. In some implementations, the upstream pressure sensor 550 is in communication with the controller system 103 on the surgical system 100. The controller system 103 may be configured to receive information from the upstream pressure sensor 550, such as pressure information, which may be indicative of phacoemulsification needle 324 occlusion. The controller system 103 may include an executable program for operating the aspiration pump motor 344 of the pump with controllable suction lift 312. The controller system 103 may receive inputs from an operator or may include pre-stored optimum targets for the aspiration flow. These target and received inputs may be a single value or a range of values. In some implementations, the controller system 103 includes a PID controller configured to control the pump with controllable suction lift 312 to mitigate pressure deviations. The controller system 103 may be in communication with and may be configured to control the operation of the pump with controllable suction lift 312. In operation, the aspiration pump motor 344 rotates the peristaltic pump head 377. The controller system 103 may control the operation of the aspiration pump motor 344. In this manner, the peristaltic pump head 377 may be rotated at any desired speed to produce any desired aspiration flow rate. When rotated, the pump with controllable suction lift 312 draws the aspiration fluid from the surgical site through the aspiration conduit 340. The controller system 103 may use the pressure information received from the upstream pressure sensor

550 to determine whether the speed of the peristaltic pump head 377 should be increased or decreased to maintain or regulate IOP. In the exemplary implementation shown in FIG.3 and FIG.4, the upstream pressure sensor 550 is located along the aspiration conduit 340 between pump 312 and the distal end 304. In this manner, the sensor 550 can accurately detect the pressure conditions in the aspiration conduit 340 very close to the surgical site. Detecting pressure conditions close to the surgical site may result in early detection of occlusion breaks, and therefore, may reduce the magnitude of post-occlusion break events. The control system 103, may detect pressure deviations in the system, such as those that may occur as a result of an occlusion in the aspiration system, and may quickly act to counter the effects of any occlusion surge. For example, the control system 103 may use the changes in pressure within an aspiration conduit, such as aspiration conduit 340, detected by the sensor, such as, for example, upstream pressure sensor 550, to detect an occlusion, such as an occluded tip. Upon detecting an occlusion (based on the pressure readings from the sensor), the control system 103 may adjust the aspiration flow using the pump with controllable suction lift 312 to reduce the effects of a post-occlusion surge. The continuous monitoring of the pressure within the aspiration conduit may result in a more consistent and predictable phacoemulsification procedure by reducing the effects of pressure deviations that occur with post-occlusion surges, that is, by immediately responding to the deviations in pressure. For example, data representing the pressure level within the aspiration conduit may be transmitted to the controller system 103. The controller system 103 may detect an occlusion when the pressure within the aspiration conduit begins to drop below a selected level. This drop in pressure beyond the selected level may be a buildup of vacuum pressure within the aspiration conduit. In response to this reduction in pressure, the controller system 103 may alter a speed of an aspiration pump, such as pump 312, in order to reduce the amount of vacuum generated within the aspiration line. A reduction in the vacuum pressure may reduce or eliminate post-occlusion surge once the occlusion clears. In conventional phacoemulsification systems, the pump is located within apart from a handpiece, such as within a

surgical console. A relatively long length of flexible conduit (six feet or more) is located between an aspiration and irrigation pump and the eye. This relatively long length of flexible conduit has high compliance. That is, the compliance of flexible conduit causes the flexible conduit to change dimensions and contract in response to changes in vacuum pressure. Also, miniature bubbles in the conduit can expand with vacuum, and collapse when vacuum is reduced adding compliance to the system. This compliance can result in surges as previously described. By incorporating the pump that interfaces with the aspiration conduit in the handpiece 112 (and placing the pump very close to the eye) and having a very short length of conduit between the pump 312 and the eye, the effects of these surges can be reduced or eliminated, thus resulting in a more consistent and predictable surgery. Furthermore, using a pump of peristaltic nature may create additional efficiencies and reduce the impact of fragments that disrupt pump flow of conventional pumps. Persons of ordinary skill in the art will appreciate that the implementations encompassed by the present disclosure are not limited to the particular exemplary implementations described above. In that regard, although illustrative implementations have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure. It is understood that such variations may be made to the foregoing without departing from the scope of the present disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a way consistent with the present disclosure.

CLAIMS:

1. An aspiration pump with controllable suction lift for aspiration of fluid and tissue fragments from inside a body cavity through an aspiration port of a surgical probe, comprising: a fluid conduit with malleable collapsible walls as a portion of a fluid path between a pump in-port and a pump out-port, a peristaltic pump head portion disposed to produce localized travelling occlusions at said fluid conduit to generate travelling fluid conduit pockets fillable with fluid and tissue fragments displacing from said pump in-port to said out-port, a vacuum lift adjustment chamber determining a sealed volume around said malleable collapsible wall of said fluid conduit said sealed volume set at a pressure level that can be lower than atmospheric pressure, said peristaltic pump head actuator portion disposed to operate said peristaltic pump head portion to displace said localized travelling occlusions of said fluid conduit in sequence along said fluid conduit between said in-port and said out-port, whereby the suction lift of said aspiration pump is controlled by said pressure level at said sealed volume inside said vacuum lift adjustment chamber.
2. Said malleable collapsible walls from claim 1 being non-expandable.
3. Said aspiration pump with controllable suction lift from Claim 1 located within a surgical handpiece.
4. Said pressure level from claim 1 being provided by a vacuum source connected to said sealed volume inside said vacuum lift adjustment chamber.
5. The pressure level from claim 1 being adjustable to control the suction lift of said aspiration pump with controllable suction lift.
6. The pressure level from claim 1 being produced by a vacuum source located at said handpiece.
7. Said pump out-port from claim 1 connected to a second vacuum source in a way that the power requirements of said aspiration pump with controllable suction lift are reduced.

8. The pressure level from claim 1 being produced by a vacuum source that is simultaneously connected to both said vacuum lift adjustment chamber and also to said pump out-port in a way that suction lift control and waste fluid extraction are provided by a single fluid conduit.

9. The peristaltic pump head actuator portion from claim 1 driven by a detachably coupled and fluidically isolated motor using magnetic coupling means for energy transmission.

10. The fluid conduit from claim 1 actuated upon in a way that said conduit localized travelling occlusions are created by kinking of said conduit.

11. The fluid conduit from claim 1 having at least one portion composed by a thin walled elastomer membrane with an embedded mesh of non-elastic fibers.

12. The fluid conduit from claim 1 having at least one portion composed by a thin walled membrane made of a non-expandable material such as polyethylene.

13. A surgical hand piece comprising: a hand graspable body; a probe operatively coupled to the hand graspable body; an aspiration passage defined through the probe and hand graspable body; and a suction pump with controllable suction lift integrated within the hand graspable body, the suction pump operable to generate an aspirated flow along the aspiration passage up to a maximum suction lift controlled by a vacuum inside a lift control chamber at the surgical hand piece to substantially maintain the pressure within the aspiration passage at substantially the selected level of pressure.

14. The surgical hand piece of claim 13, wherein the assisted pump with controllable suction lift has a peristaltic head operatively coupled with a peristaltic conduit having substantially flexible inelastic walls inside a lift control chamber.

15. The lift control chamber from claim 13 receiving a suction lift control pressure from a pressure source.

16. The lift control pressure from claim 15 provided through an aspiration tubing from a base housing said tubing also dedicated to remove waste fluid from the handpiece.

17. The lift control pressure from claim 15 provided through an aspiration tubing from a syringe said tubing also dedicated to remove waste fluid from the handpiece.

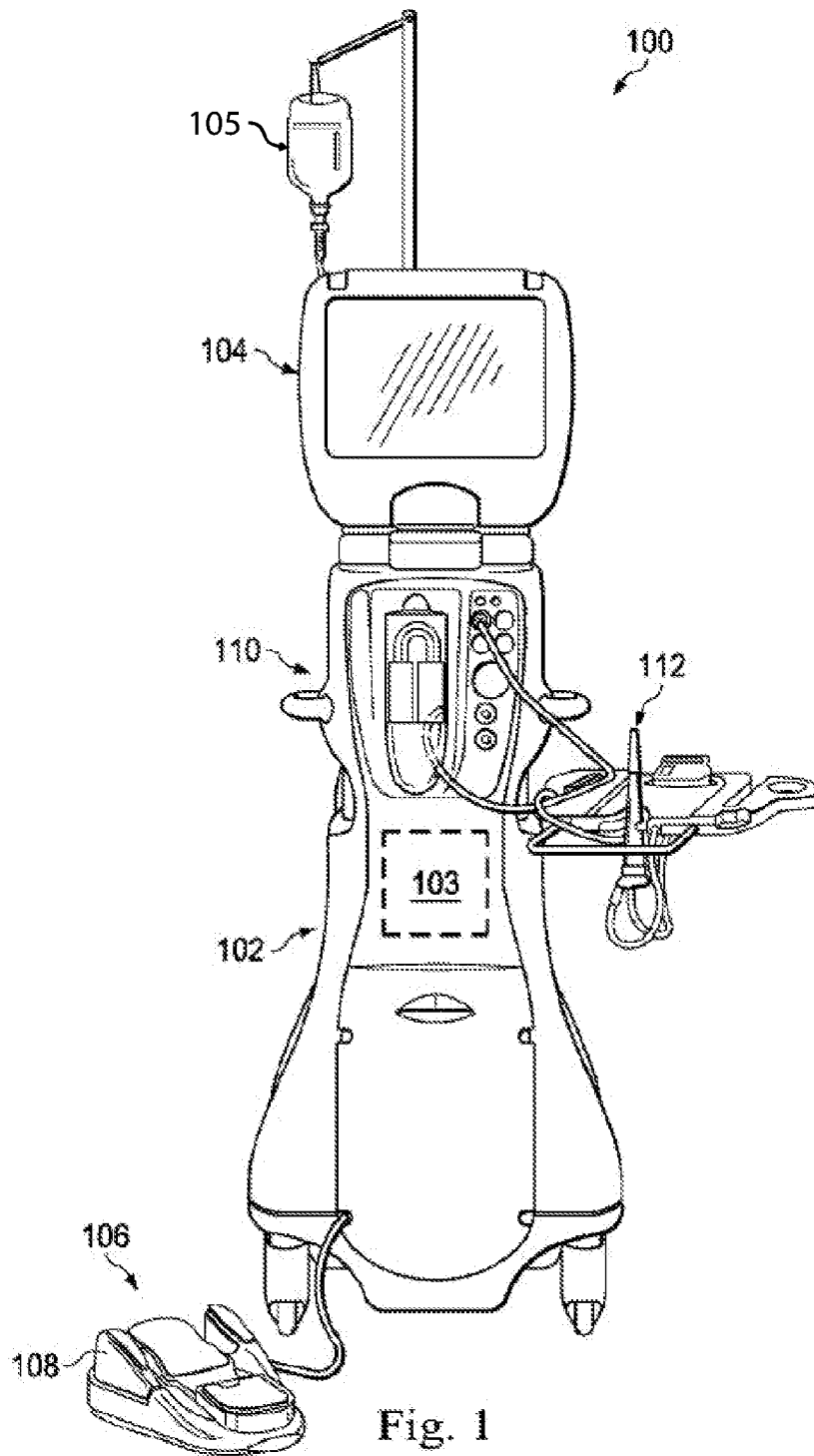


Fig. 1

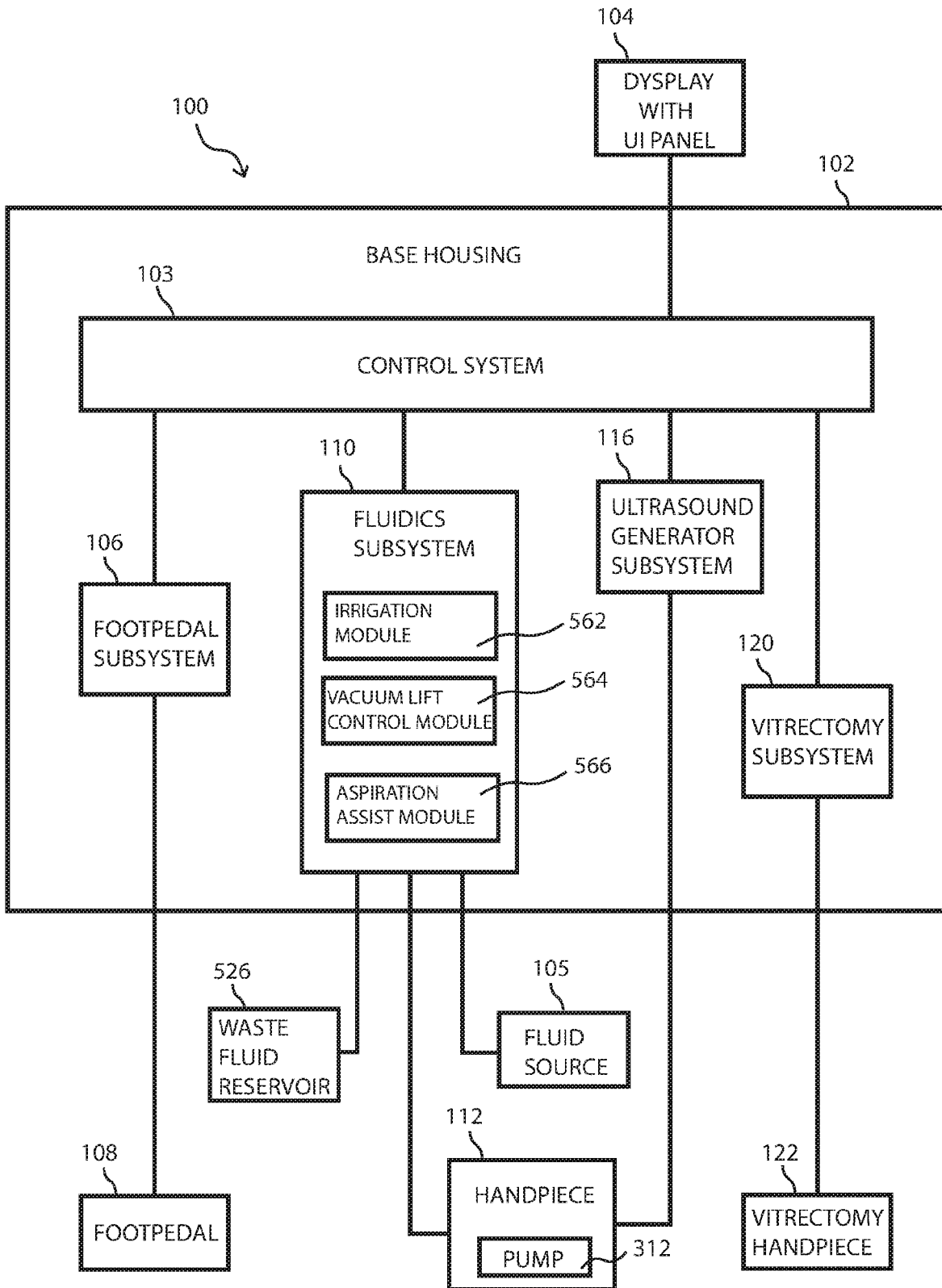


FIG. 2

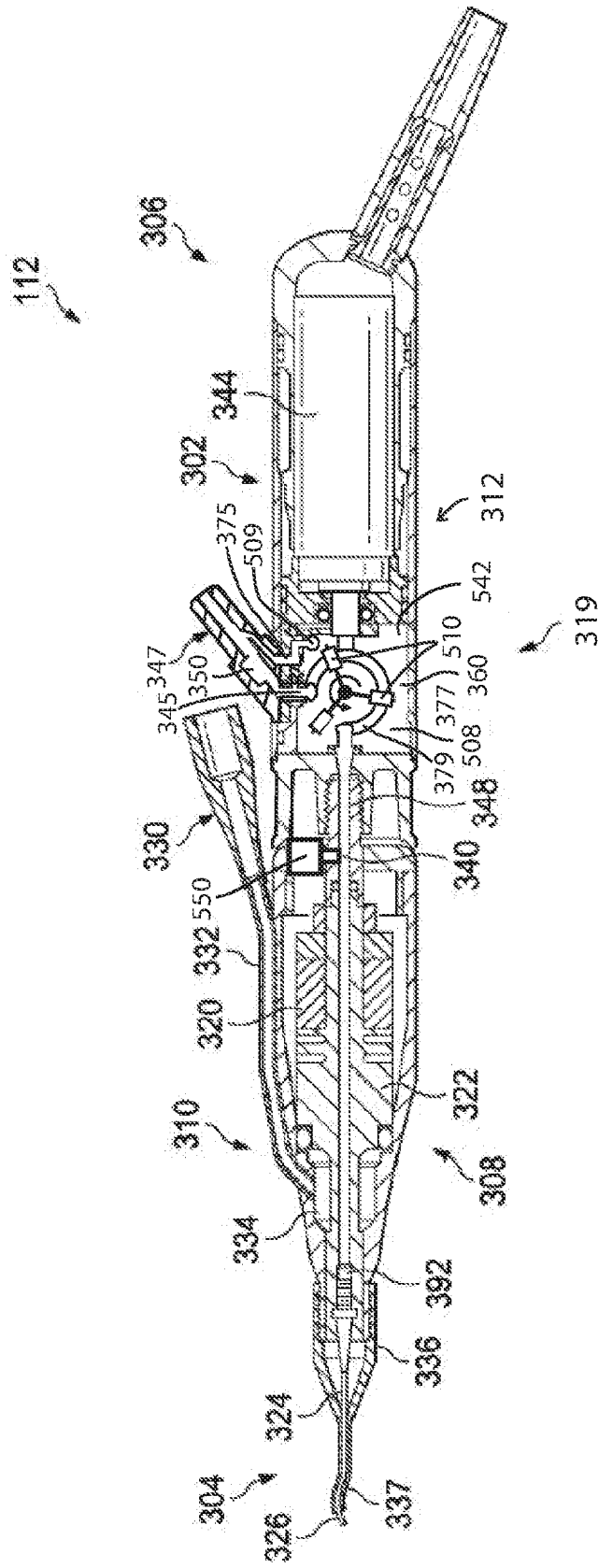


Fig. 3

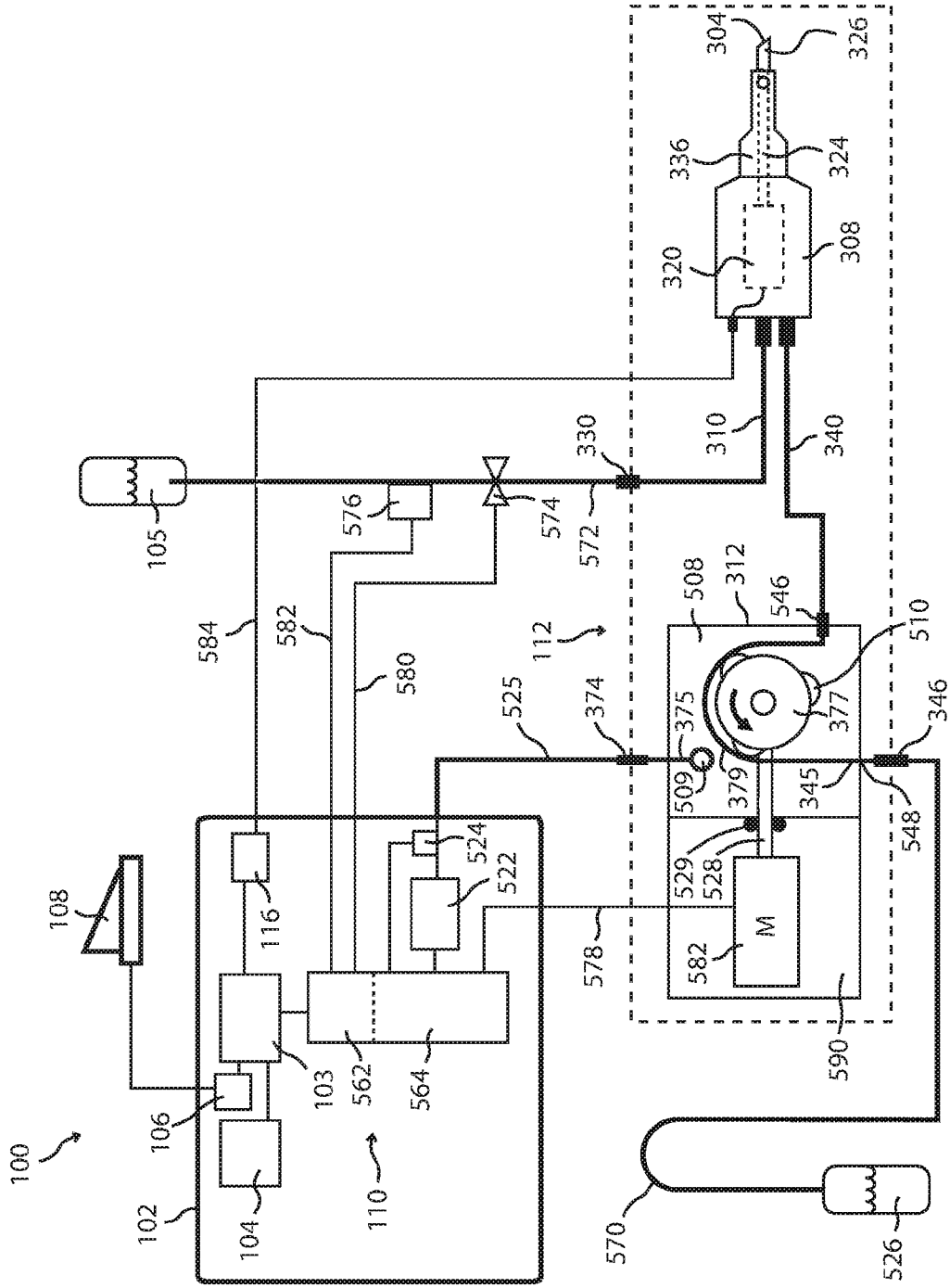


FIG.6

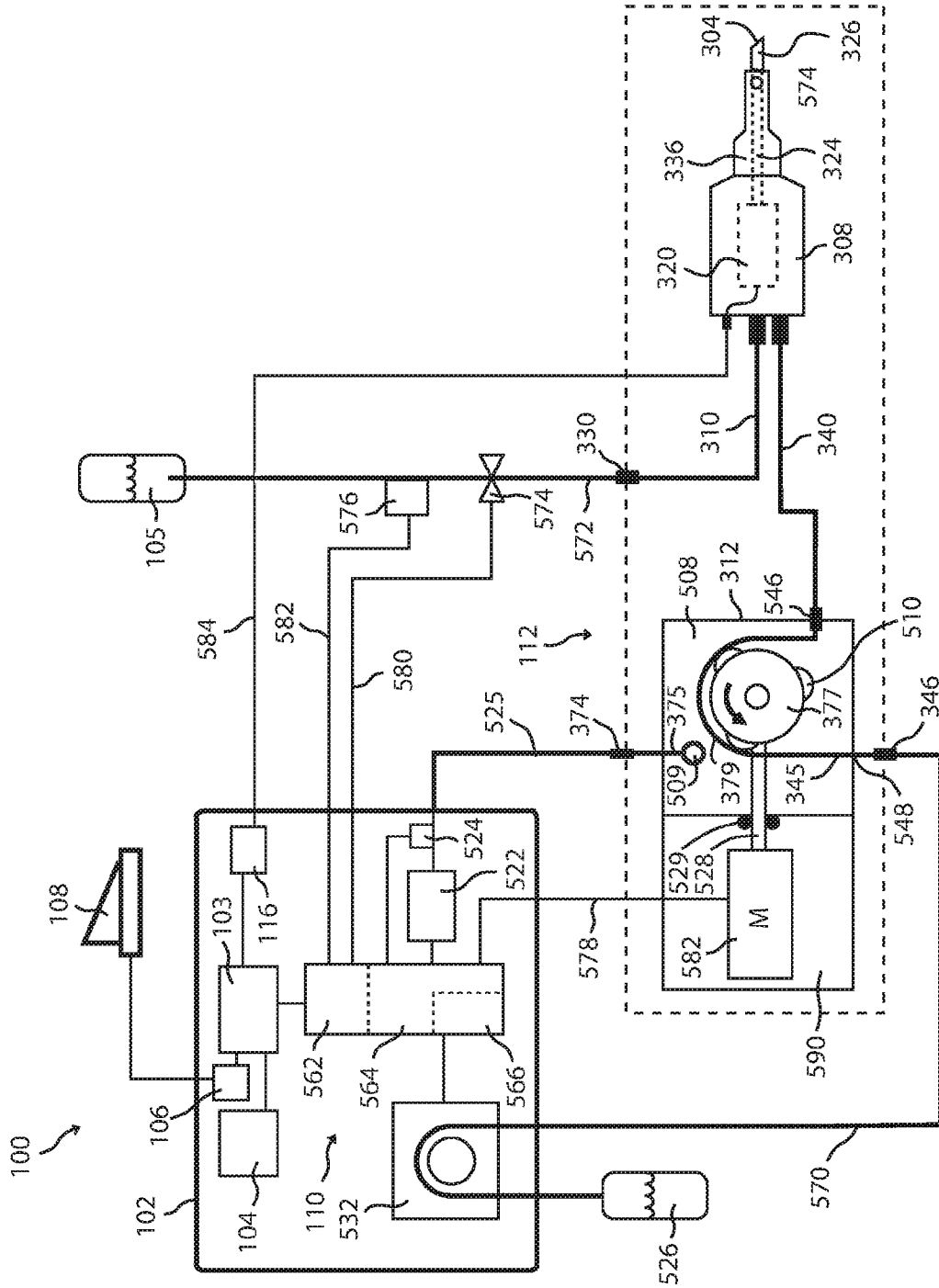


FIG. 7

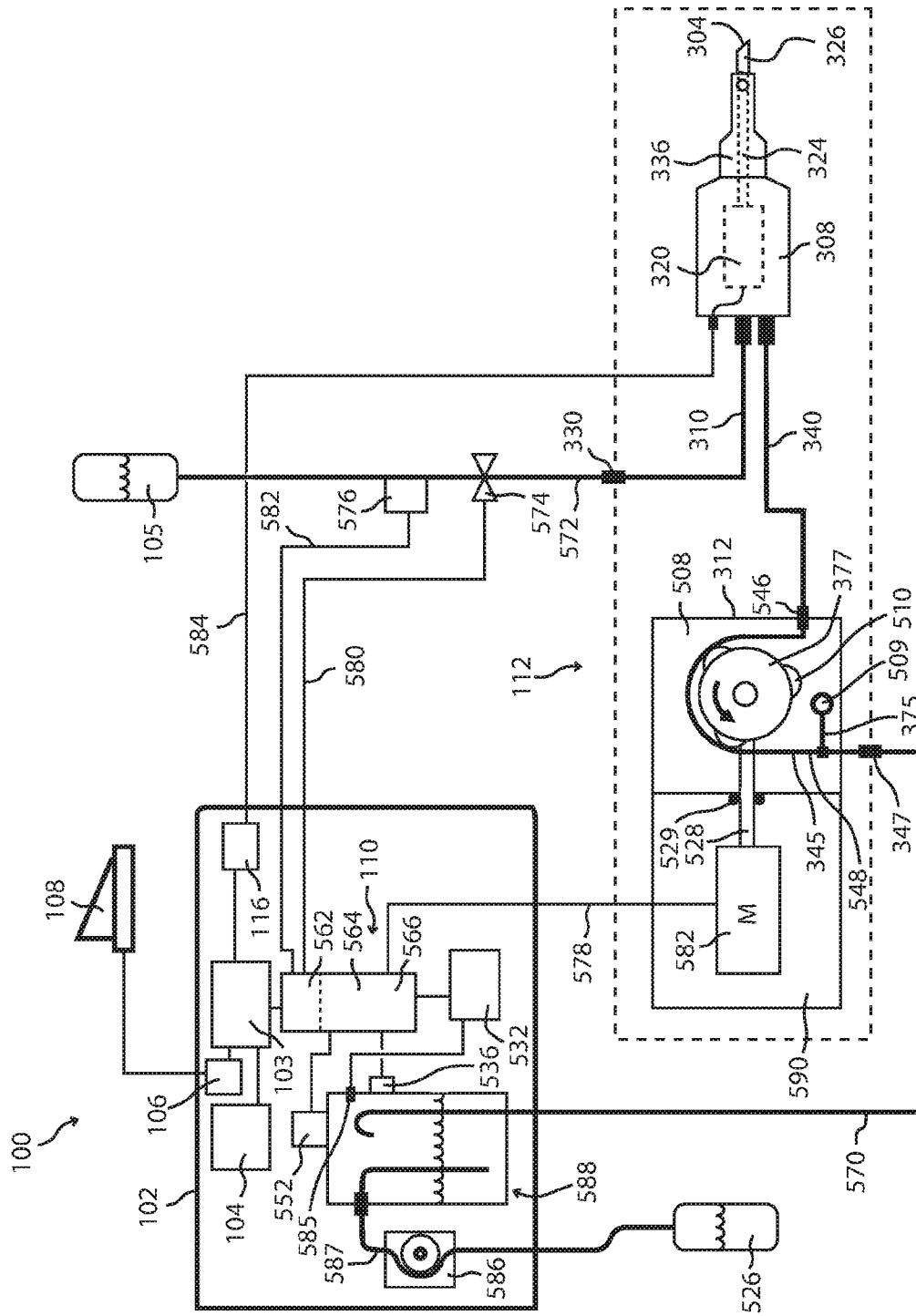


FIG. 8

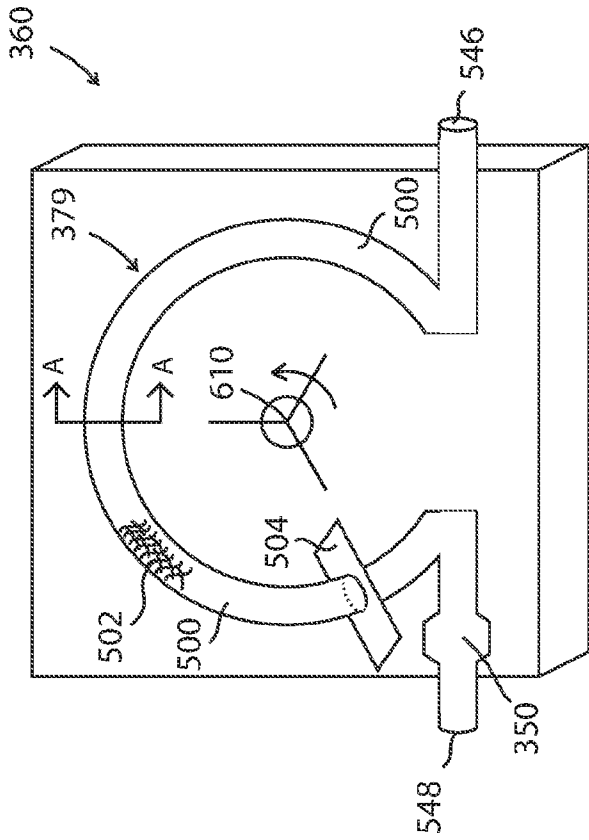


Fig. 9

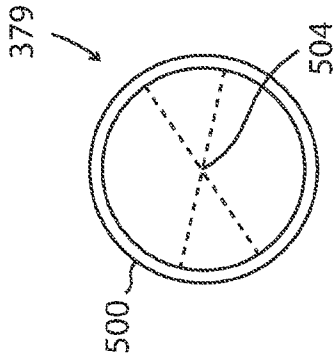


Fig. 10

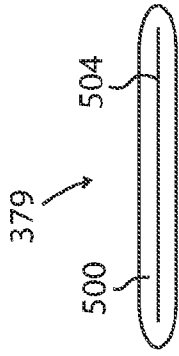


Fig. 11

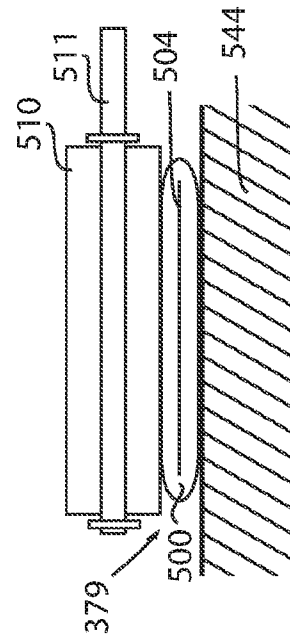


Fig. 12

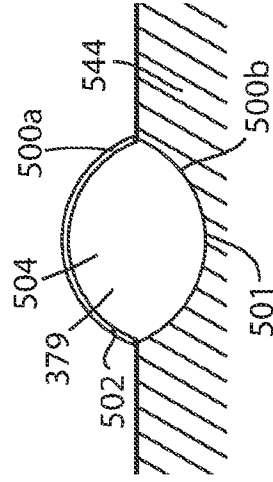


Fig. 13

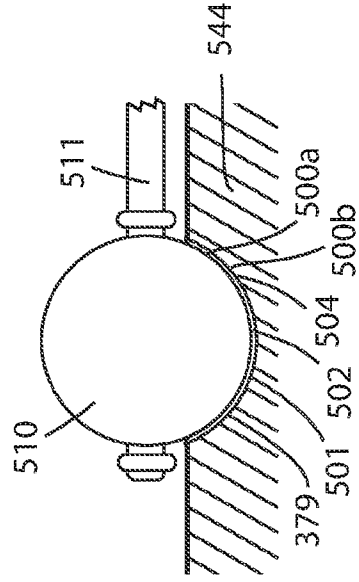


Fig. 14

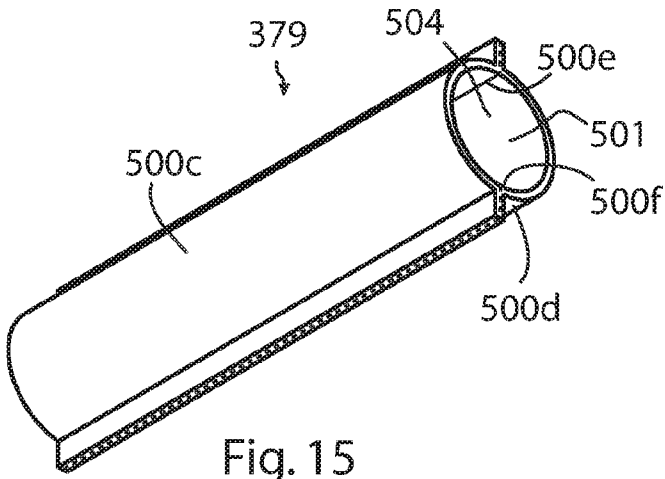


Fig. 15

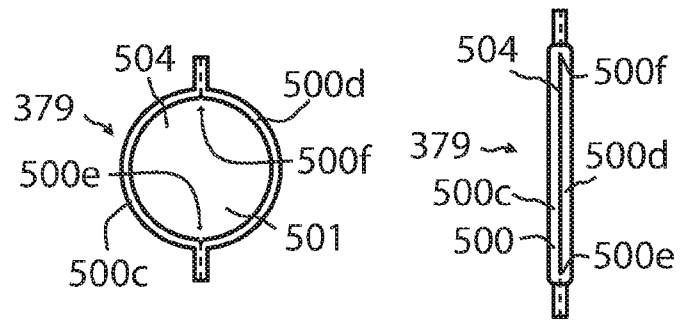


Fig. 16

Fig. 17

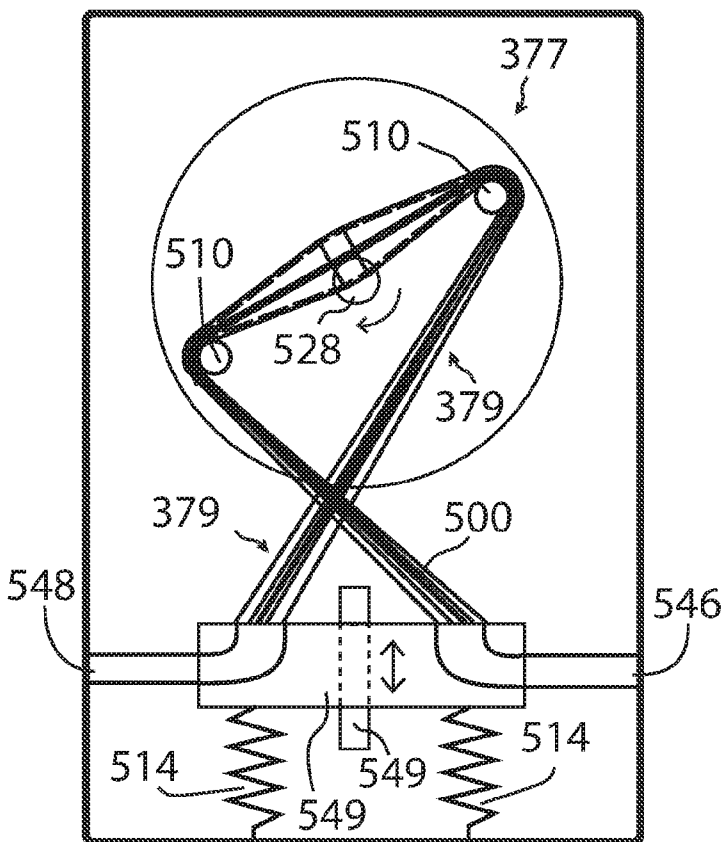


Fig. 18a

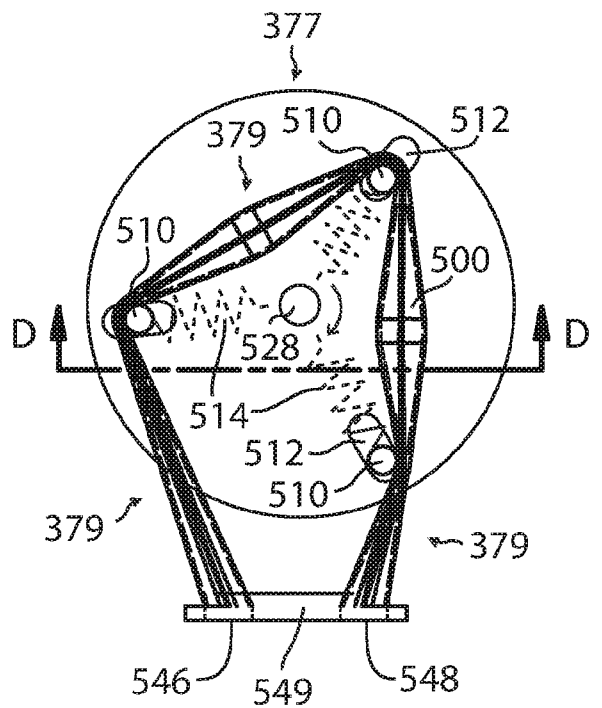


Fig. 18b

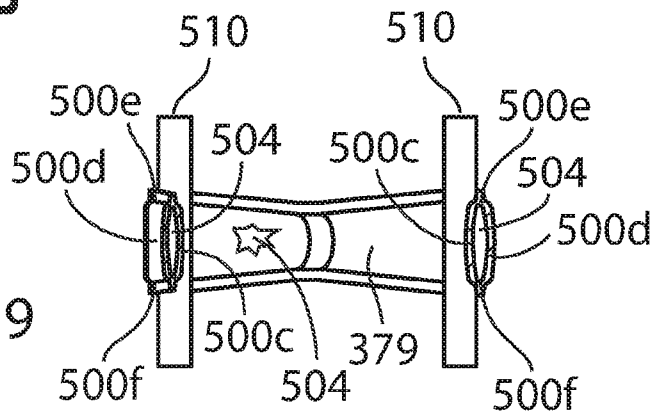


Fig. 19

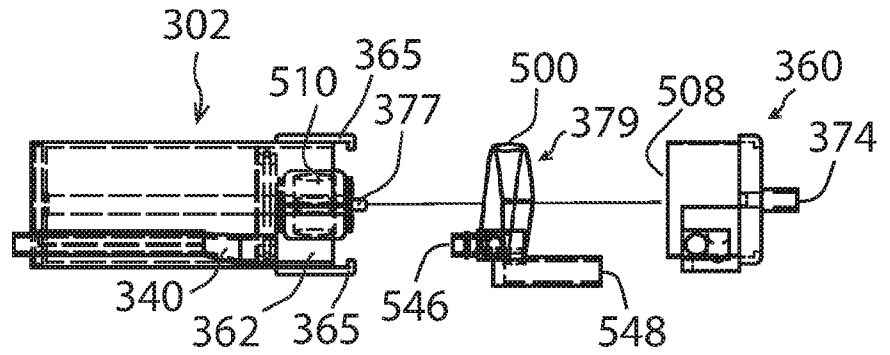


Fig. 20

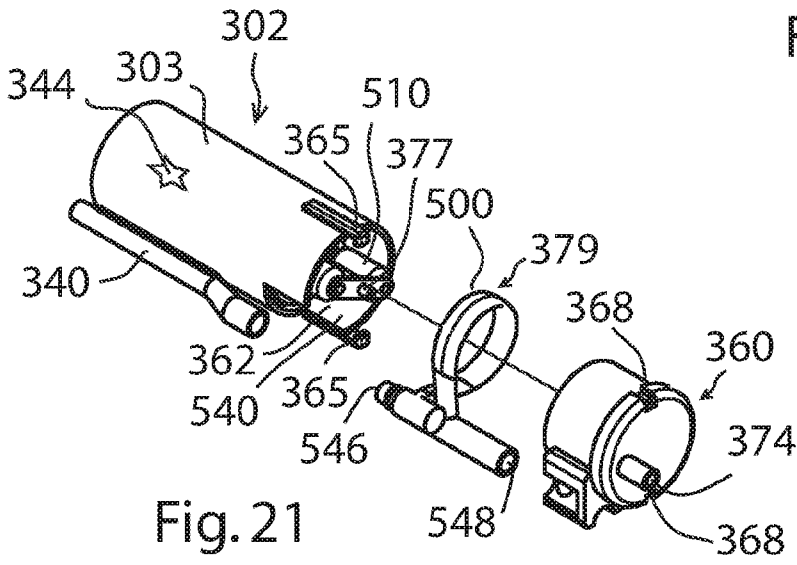


Fig. 21

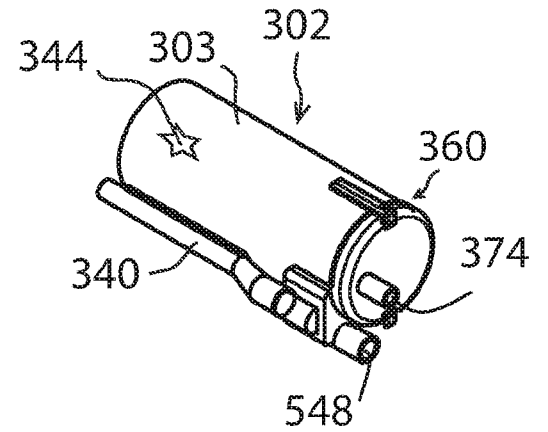


Fig. 22

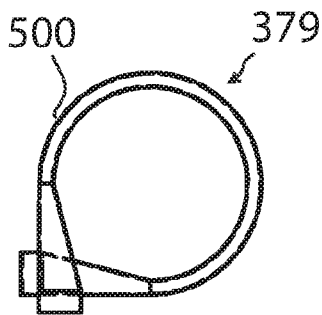


Fig. 23

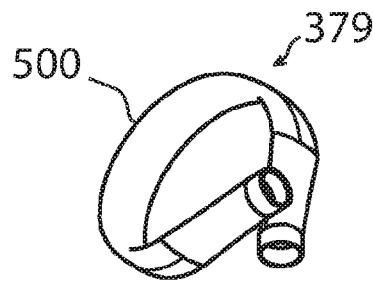


Fig. 24

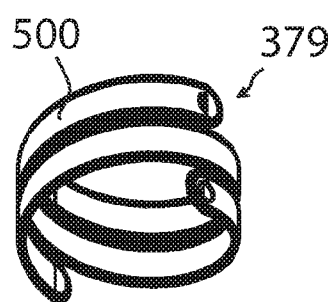


Fig. 25

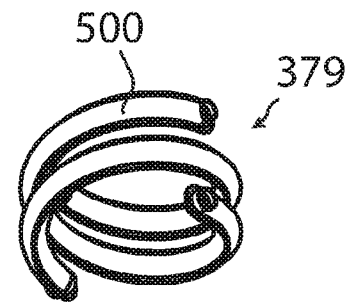
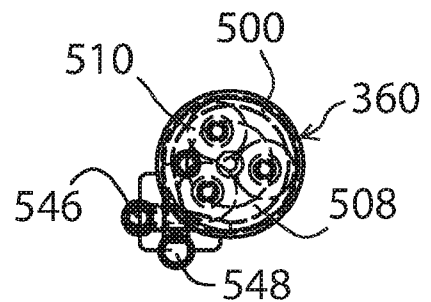
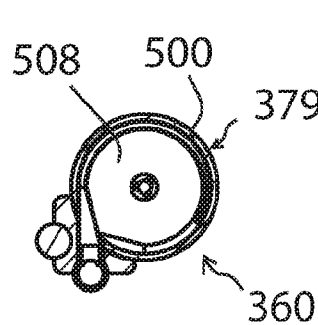
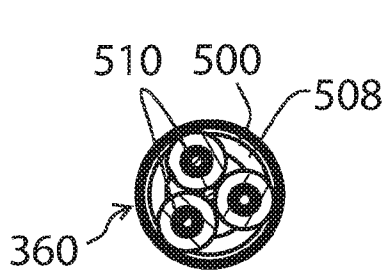
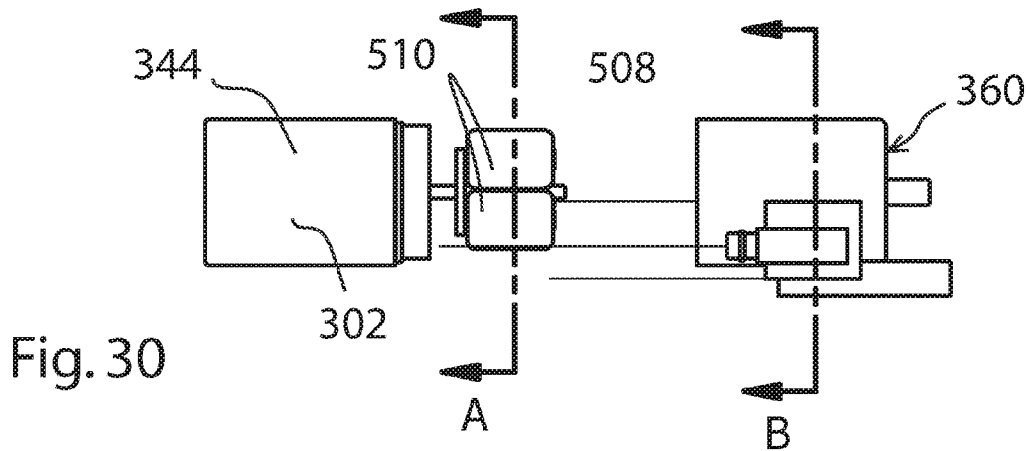
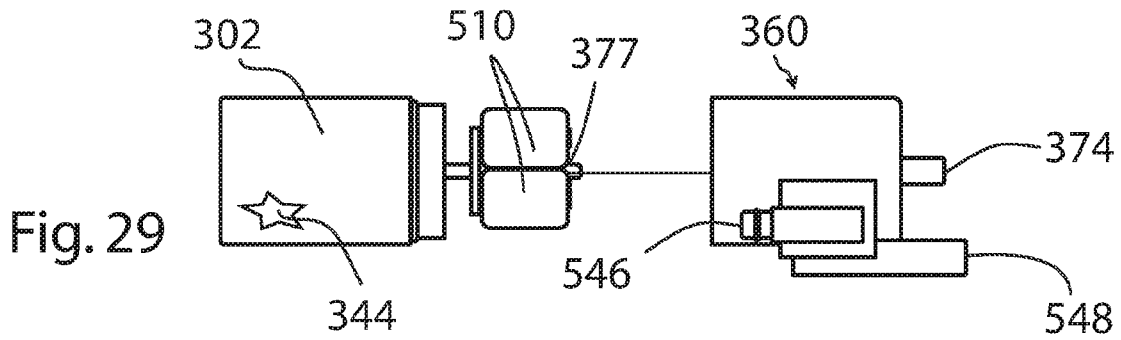
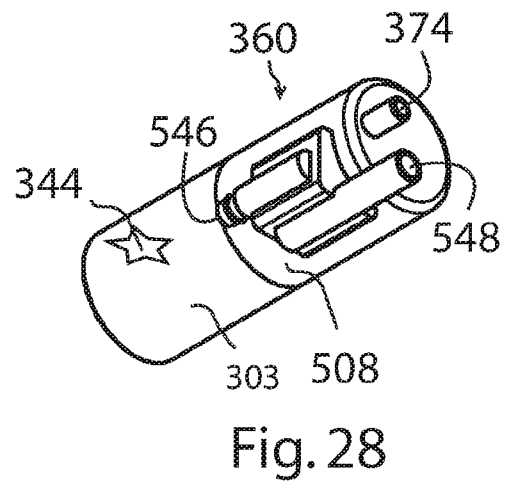
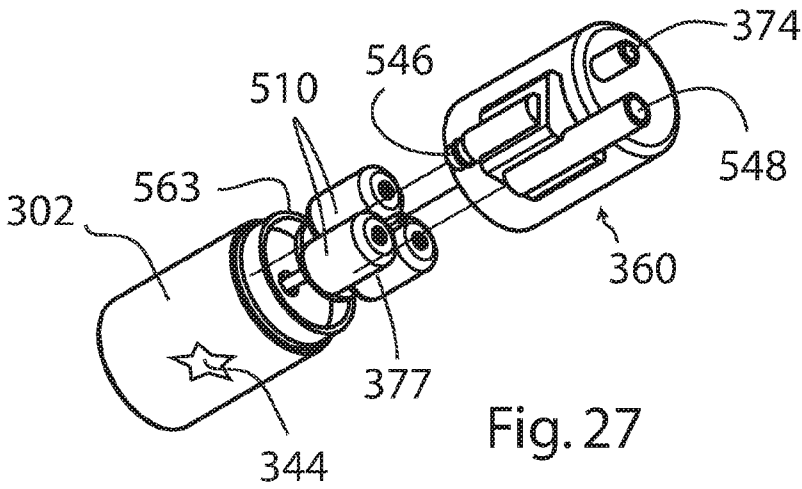


Fig. 26



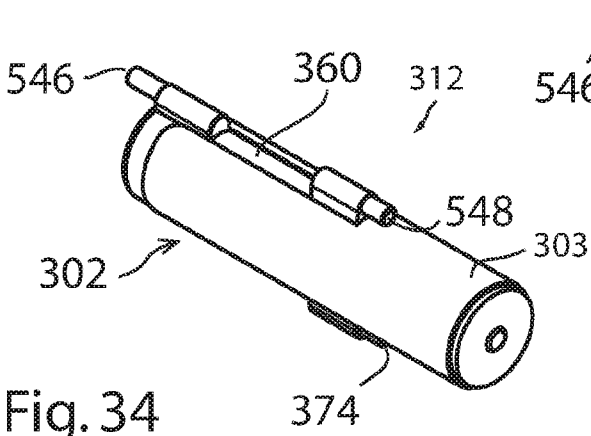


Fig. 34

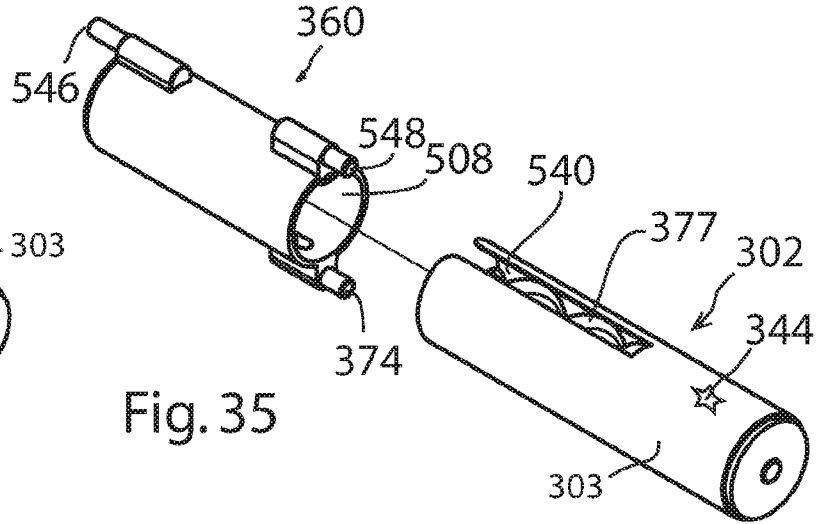


Fig. 35

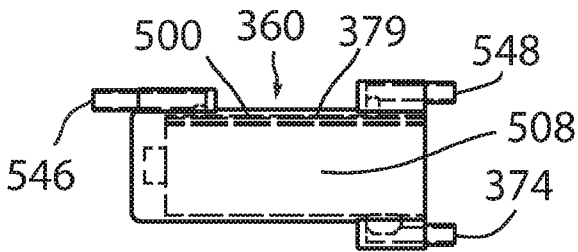


Fig. 36

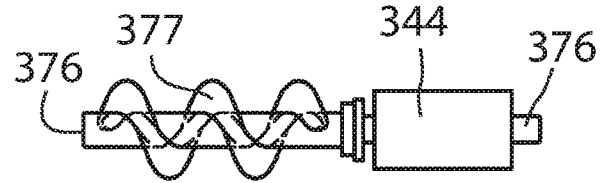


Fig. 37

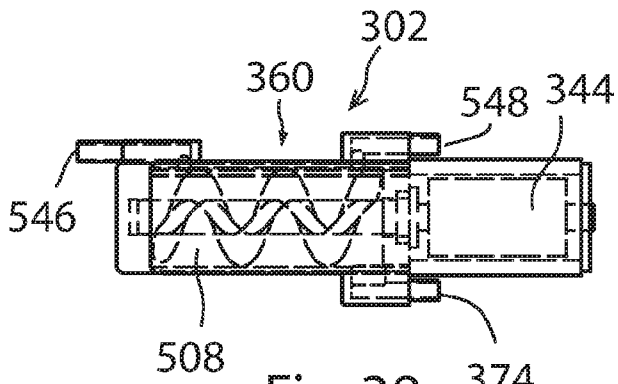


Fig. 38

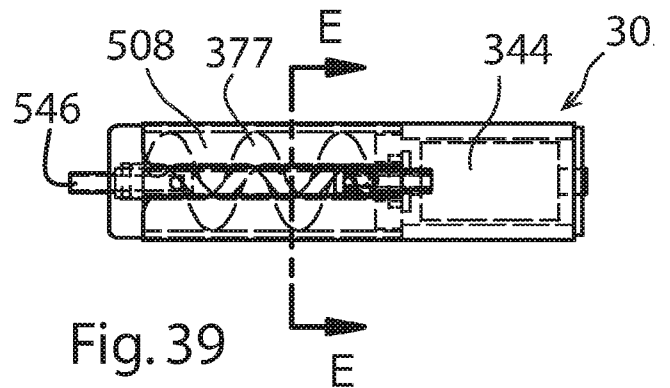


Fig. 39

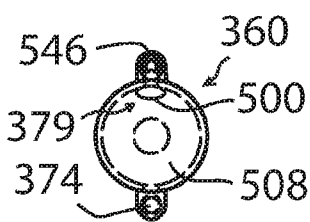


Fig. 40

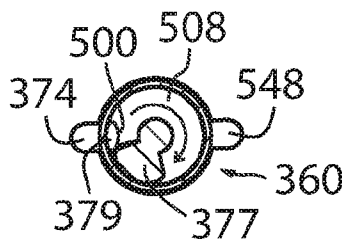


Fig. 41a

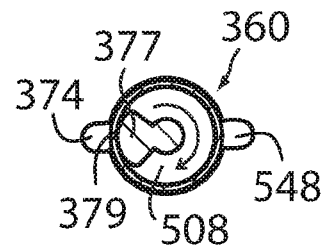


Fig. 41b

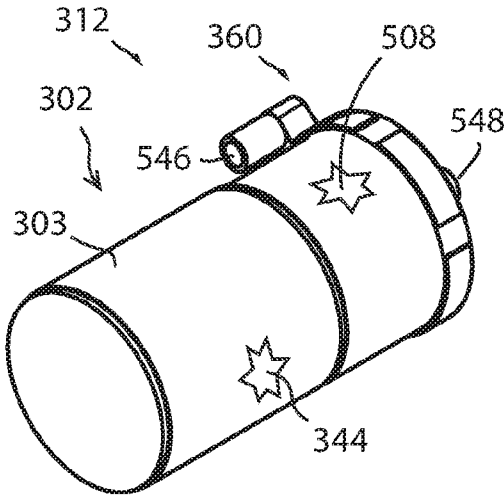


Fig. 42

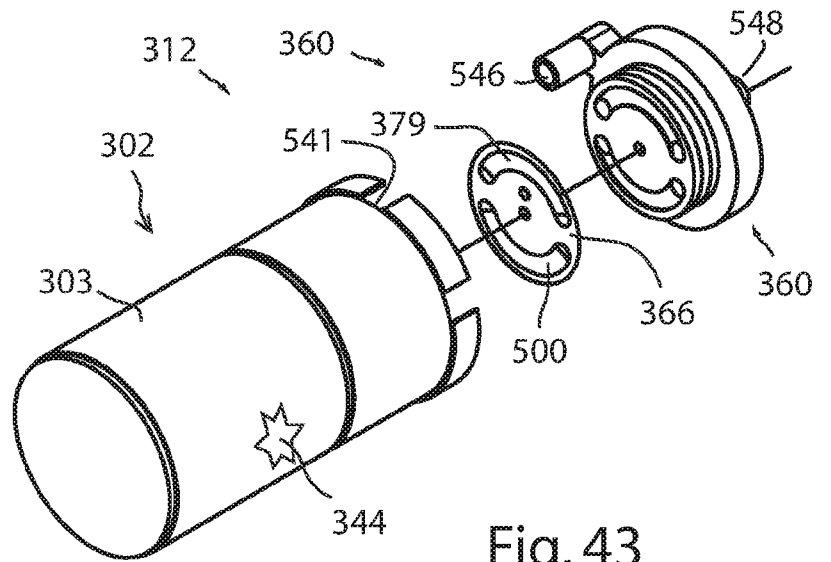


Fig. 43

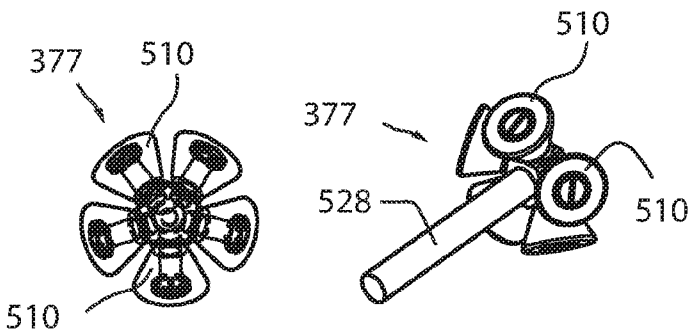


Fig. 44a

Fig. 44b

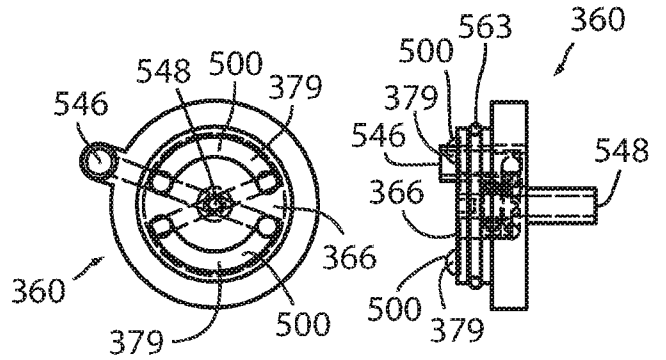


Fig. 45a

Fig. 45b

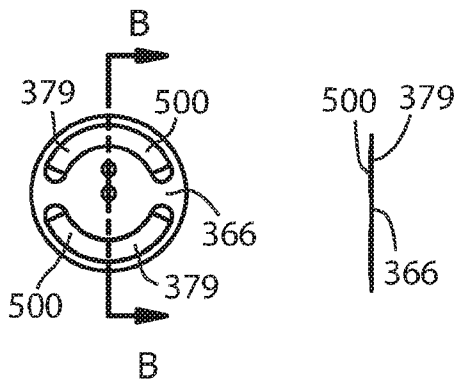


Fig. 46a

Fig. 46b

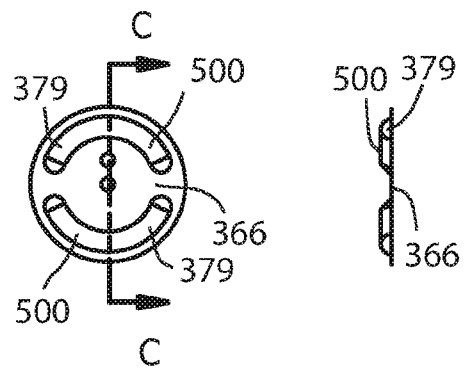


Fig. 47a

Fig. 47b

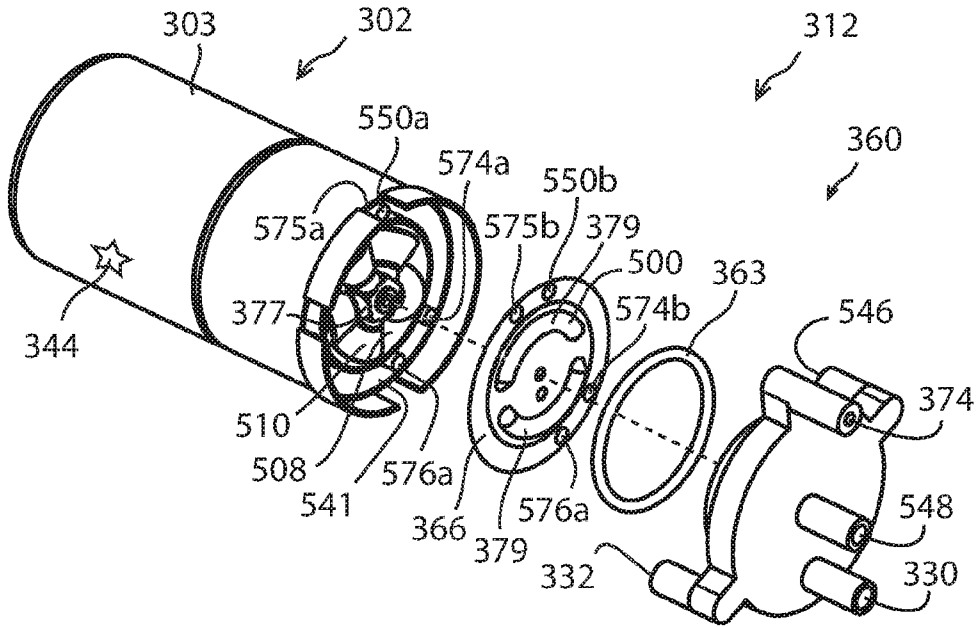


Fig. 48

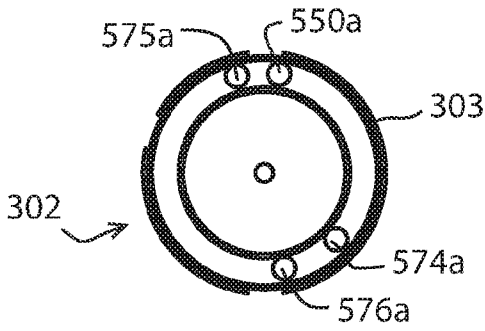


Fig. 49

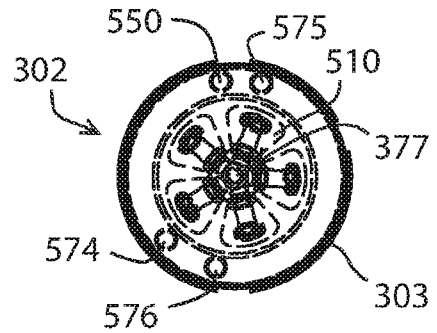


Fig. 50

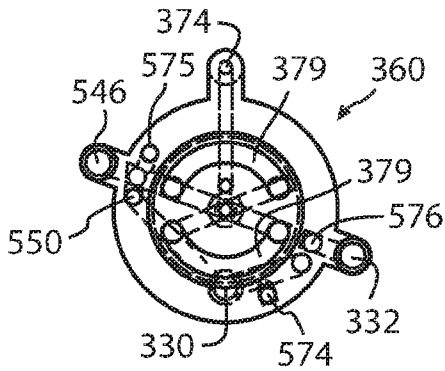


Fig. 51

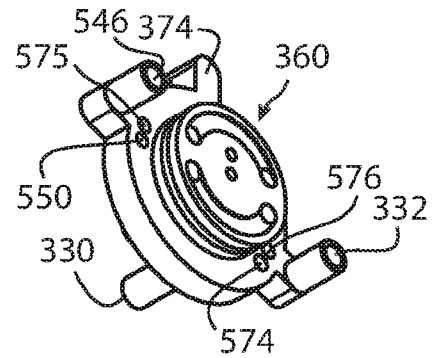


Fig. 52

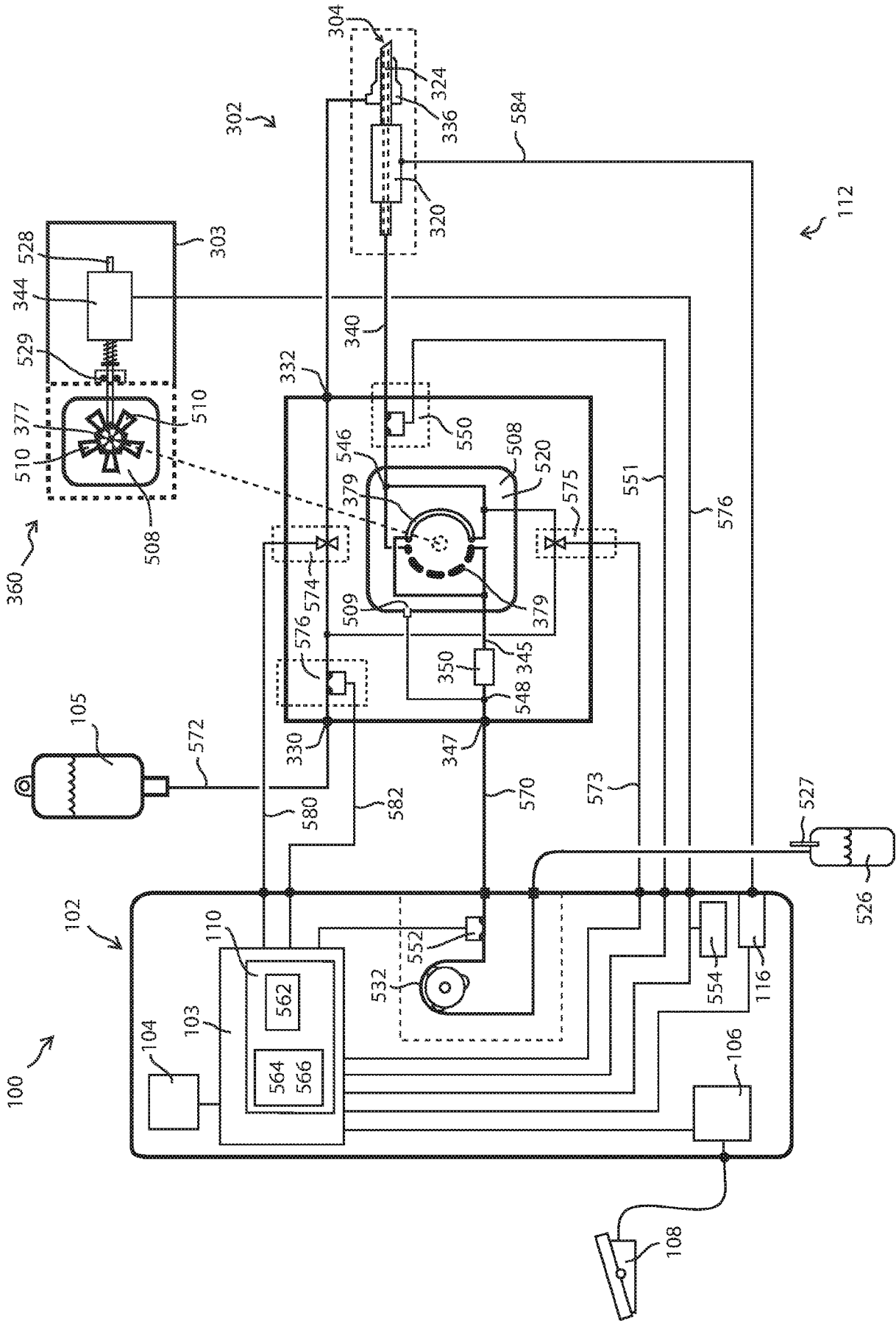


FIG. 53

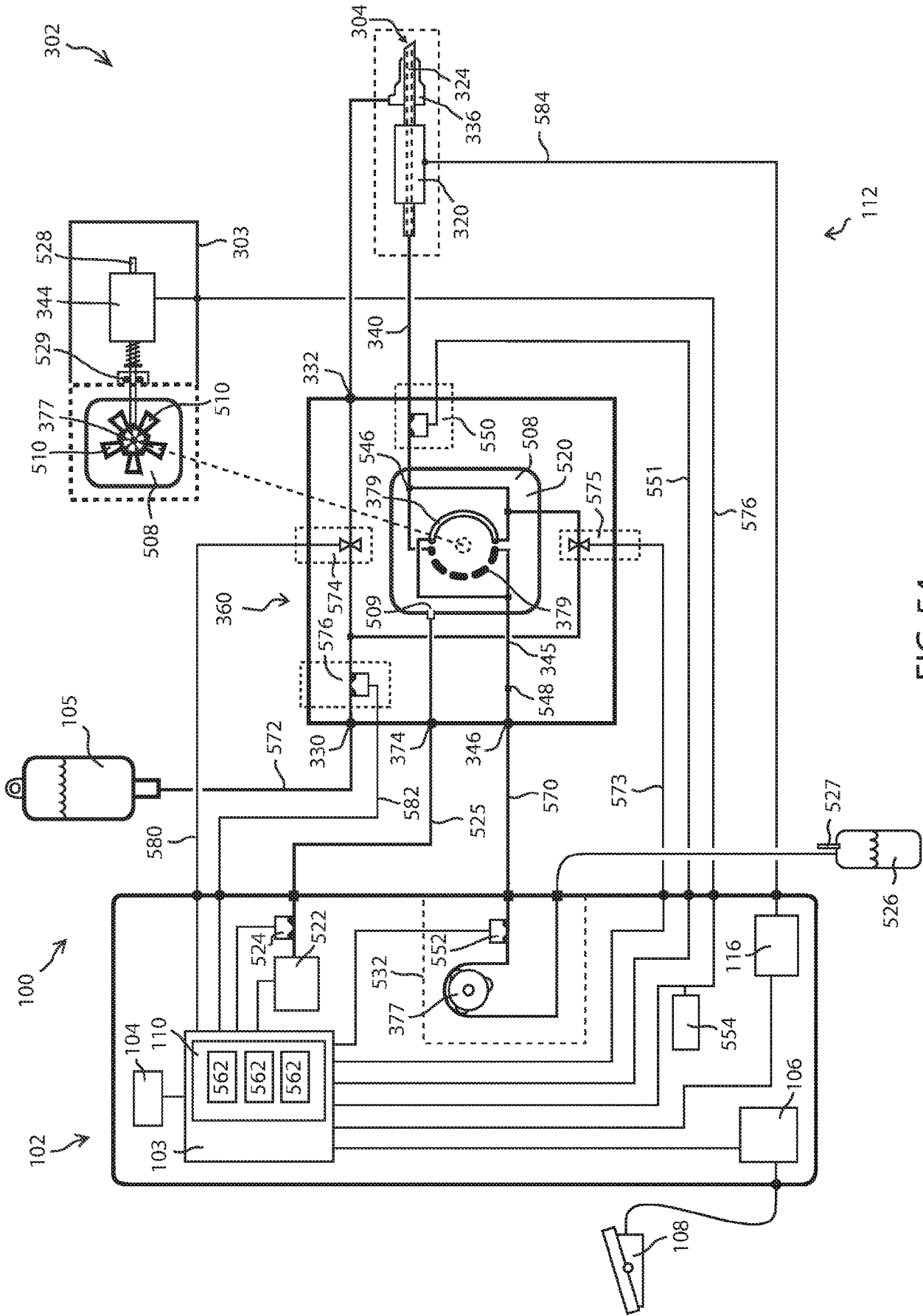


FIG. 54

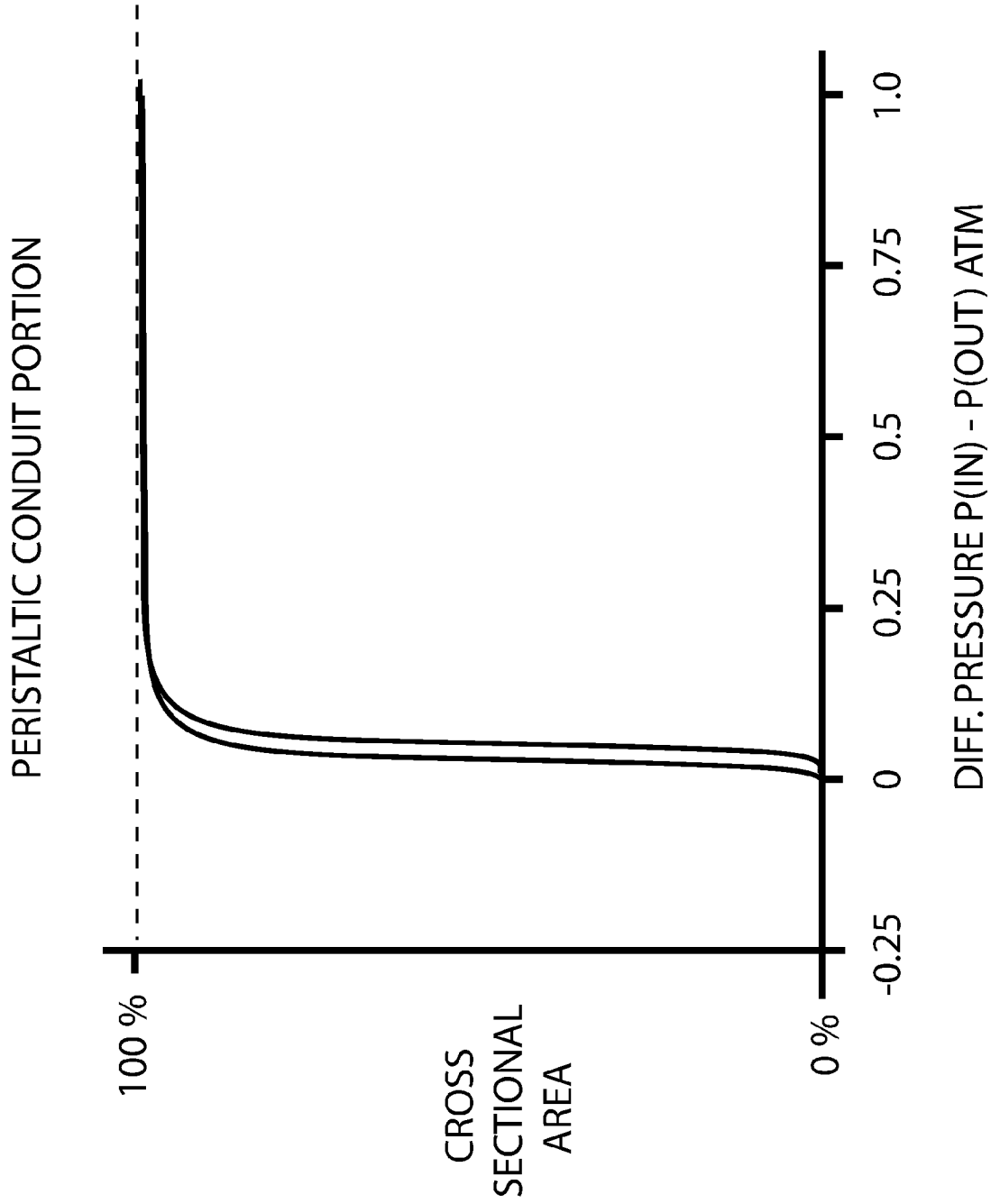


FIG.55

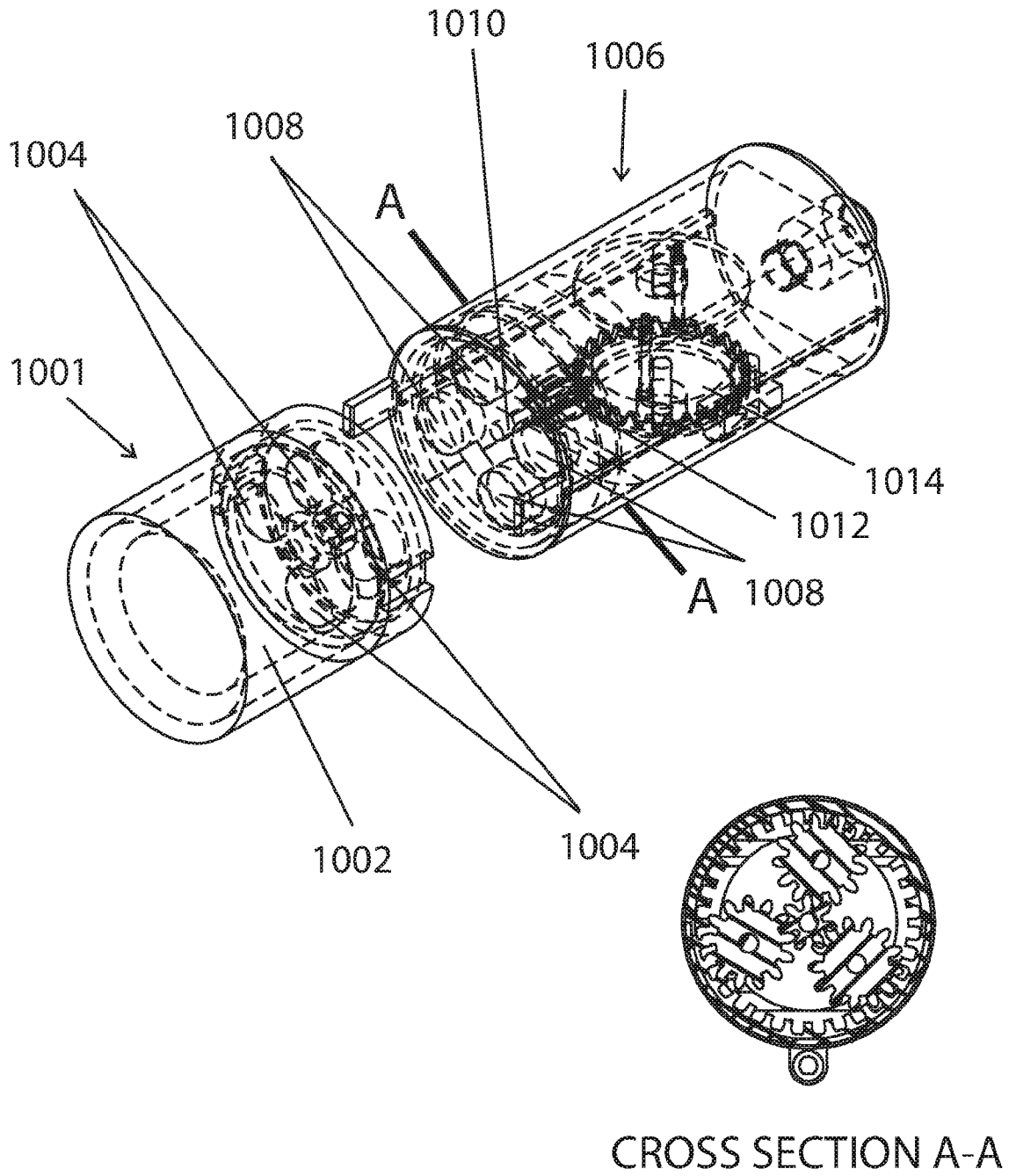


FIG. 56

