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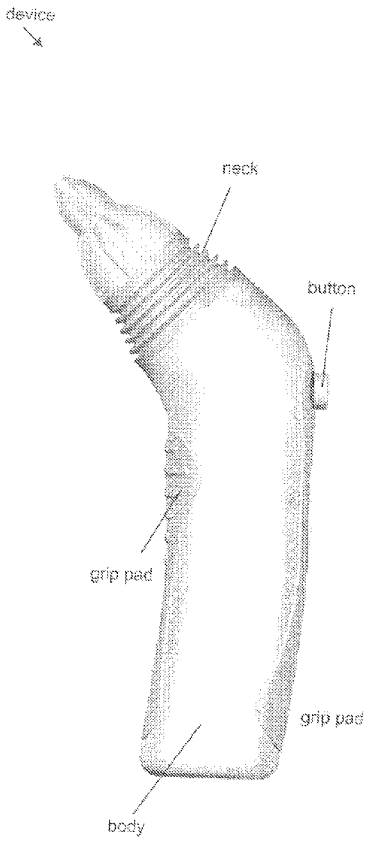
(54) Title: IRRIGATION AND ASPIRATION DEVICE AND METHOD

(57) Abstract: An irrigation and aspiration system is disclosed. The system can be configured to aspirate and irrigate alone, sequentially or concurrently. The system can be configured to aspirate and irrigate the nasal cavity. The system can be manually controlled. The system can have removable and easily cleanable reservoirs for aspirant and irrigant.



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TITLE OF THE INVENTION

IRRIGATION AND ASPIRATION DEVICE AND METHOD

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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 60/857,457 filed 6 November 2006, and U.S. Provisional Application No. 60/944,079, filed 14 June 2007, both of which are incorporated by reference herein in their entireties.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to the field of medicine, specifically nasal aspiration and irrigation, as administered in the hospital as well as in the home. In particular, the device may be able to aspirate and irrigate simultaneously through one nozzle. Both actions can be controlled by one dual-function switch.

2. Description of Related Art

[0003] Nasal congestion is a ubiquitous problem in children and adults. Viral illnesses and environmental allergies in about 100 million Americans per year cause myriad symptoms including rhinitis (i.e., nasal inflammation), which causes congestion, rhinnorhea, and sinus blockage. This can cause sinusitis, but more commonly, irritation, pain, and nasal cavity blockage, which causes poor sleeping and feeding in infants and general discomfort and malaise in adults. Medical treatments are available, but inherently have side effects and financial costs. Relief of congestion can be met by blowing the nose, which is eventually irritating to the adult and difficult or impossible for a child or infant.

[0004] It has been shown that nasal suctioning, following saline irrigation, is an effective way of relieving symptoms and signs of rhinitis. Nasal suctioning can circumvent the side effects of medicines and irritation-or impossibility-of nose blowing. Manual aspirators have long been used in infants for this. However, they do not offer strong enough vacuum nor adequate evacuation time. As a result, they are variably efficacious and can be

awkward and frustrating to use. Typical sinus irrigators designed for adults with sinusitis do not circumvent the problem of painful evacuation or blowing.

[0005] Furthermore, nasal congestion from viral respiratory infections causes difficulties with sleeping and eating in infants as they are obligate nose breathers. This leads to poor nutrition and restlessness which disrupts both the child's well being and the family's functioning. Worse, unresolved nasal congestion as part of an infant's viral syndrome can lead to emergency department visits or hospitalization for supplemental oxygen, frequent suctioning, and parenteral nutrition.

[0006] Several strategies are used to resolve nasal congestion. Several studies have demonstrated futility of cold medications in relieving symptoms, and most parents learn that nasal irrigation and suctioning is the best option. Routine nasal irrigation improves symptoms in adults with chronic rhinosinusitis as well as children with allergic rhinitis. Additionally, several studies have shown that saline irrigation improves nasal ciliary motility. It is thought that the saline draws fluid from the submucosal and adventitial space decreasing airway edema and softening the mucus, allowing easier suctioning. Additionally, the saline is thought to stimulate channels in the cell membrane which improves the cell's function.

[0007] Such a combination of saline irrigation and suctioning has proven benefits, especially for infants with bronchiolitis. Most studies evaluating nasal suctioning used hospital's central "wall" suction and some studies even used deep nasopharyngeal suctioning, both of which are not routinely available for home use. The studies demonstrated that appropriate suctioning reduces the need for further interventions, such as nebulizations, oxygen supplementation and admissions.

[0008] In contrast to hospital wall suction, manual nasal aspirators are available for home use. Their maximal negative pressure and flow rates are low, requiring repeated movements to and from the nose. Both parameters contribute to their imperfect quality: more pressure has been shown to be optimal (80-100mmHg) and the short duration of their action requires repeated attempts back and forth, rendering them awkward.

[0009] Typical bulb suction syringes offer some suction, but brief and inadequate pressures can limit its utility. Additionally, the narrow and long stem allow for the possibility of mucosal damage as well as an inadequate seal at the nares. Some manual aspirators have circumvented that problem by developing better nasal tips that have improved seal and safety.

[0010] An existing manual device can sequentially (not simultaneously) deliver an agent followed by aspiration of the agent and orifice contents. It allows for neither the simultaneous activation of both functions nor the higher vacuum/flow as with a motorized device.

[0011] Still other devices have dual actions, though not designed for nasal cavities and not all-contained. For example, a hand-piece exists for surgical aspiration and irrigation. It is for surgical purposes (celioscopy) and not a home device. It requires outside sources of both vacuum and irrigant and can only perform one action at a time.

[0012] Another device describes a system for irrigating and aspirating surgical wounds. It consists of an elongate flexible suction and irrigation tip as opposed to our nozzle head configuration. The flexible shaft has a suction lumen next to or inside an irrigation lumen. The trigger controls only the irrigation mechanism while an outside source provides constant, and not intermittent, suction.

[0013] U.S. Patent No. 4,776,840 is a hand-held evacuator and irrigation device also for surgical purposes only. Its sources of vacuum and irrigant are also outside the housing, and needs two buttons to operate the two functions. The two functions are also delivered by two different ports, not one.

[0014] U.S. Patent No. 5,649,530 discloses a nasal cleaning device that had an atomizing chamber within the nozzle and a chamber for collecting aspirant proximal to the chamber. The aspirant and irrigant can mix together within the nozzle. This can result in unsanitary irrigant delivered to the nose.

[0015] Finally, U.S. Patent No. 6,893,414 is an integrated infusion aspirator device also used for surgical procedures specifically addressing post-surgical pain by cleaning out surgical wounds. It allows for concurrent irrigation and aspiration of wound sites for any internal body wound. It also relies on outside sources of vacuum and irrigant.

SUMMARY OF THE INVENTION

[0016] A self –contained motorized device that offers a continuous or intermittent suction as well as a a continuous or intermittent on-demand irrigant delivery to the nasal passages is disclosed. The suction and the irrigant deliver can both be out of the same nozzle. The suction and irrigation can be actuated by an ergonomically designed dual function switch. The device can have a removable irrigant and/or suction module.

[0017] A device for irrigating and aspirating biological tissue and/or secretions is disclosed. The device has a body, a nozzle articulatably connected to the body, an

electronically driven fluid control system, and a manual control. The manual control can be configured to control the fluid control system. The fluid control system can be contained in the body. The fluid control system can be configured to irrigate at an irrigation pressure and aspirate at an aspiration pressure

[0018] The device can also have a head articulatably connected to the body. The nozzle can be on the head. The head can be attached to the body. The fluid control system can be configured to simultaneously irrigate and aspirate. The fluid control system can be configured to vary the irrigation pressure at more than one non-zero pressure. The fluid control system can be configured to vary the pressure of aspiration at more than one non-zero pressure.

[0019] The manual control can control irrigation and aspiration. The manual control can be configured to be usable with a single digit (e.g., finger or thumb). The entire device can be handheld. The body can have a power source. The body can have a first motor.

[0020] The device can have a pump. The pump can have a piston, a blower, a turbine, a fan, one or more diaphragms, or bellows, or combinations thereof. The pump can be electrically powered. The pump can be a DC pump.

[0021] The fluid control system can have a first reservoir having a first reservoir volume. The first reservoir can be removably attached to the body. The first reservoir can have an irrigant. The fluid control system can have a second reservoir having a second reservoir volume. The second reservoir can be removably attached to the body. The second reservoir can have an aspirate. The second reservoir volume can be the same size as, smaller, or larger than the first reservoir volume.

[0022] The control can have a button. The button can be translatable in more than one dimension. The button can have a slide. The button can have a rocker switch. The button can have a wheel. The button can be depressible. The button can be configured to provide aspiration and irrigation control.

[0023] The device can have an aspiration conduit and an aspiration port in fluid communication with the aspiration conduit. The aspiration port can be on or in the head.

[0024] The device can have an irrigation conduit and an irrigation port in fluid communication with the irrigation conduit. The irrigation port can be on or in the head.

[0025] A method for irrigating and aspirating the nose is also disclosed. The method can include simultaneously irrigating at an irrigation pressure inside the nose with a device and aspirating at an aspiration pressure inside the nose with the device. The method can also include separately controlling the irrigation and aspiration with a button.

[0026] The separately controlling can include using a digit. The simultaneously irrigating and aspirating can include varying the irrigation pressure between non-zero irrigation pressures. The simultaneously irrigating and aspirating can include varying the aspirating pressure between non-zero aspiration pressures.

[0027] The device can have a body connected to a head, and the method can include articulating the head with respect to the body. The method can include holding the entire device in a hand.

[0028] The method can also include storing in the device a fluid to be irrigated. The method can also include storing in the device a fluid aspirated from the nose.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Figure 1 illustrates a variation of the irrigation and aspiration device.

[0030] Figure 2 is a cut-away schematic view of a variation of the of the irrigation and aspiration device.

[0031] Figure 3 is a cut-away view of a variation of the head.

[0032] Figure 4 is a partially see-through view of a variation of the head.

[0033] Figure 5 is a partially see-through cut-away view of the variation of the head of Figure 4.

[0034] Figure 6 is a cut-away view of a variation of the head.

[0035] Figure 7 is a cut-away view of a variation of the head.

[0036] Figure 8 is a close-up cut-away view of the variation of the head of Figure 7.

[0037] Figure 9 is a close-up end perspective view of a variation of the irrigation and atomizing conduits.

[0038] Figure 10 is a perspective partially see-through view of a variation of the head and the irrigation conduit.

[0039] Figure 11 is a front quarter partially see-through view of the variation of the head and the irrigation conduit of Figure 10.

[0040] Figures 12 and 13 are, respectively, side and off-center front partial see-through views of the head of Figure 10.

[0041] Figure 14 illustrates an end perspective view of a variation of the head.

[0042] Figures 15 and 16 illustrate variations of the head.

[0043] Figures 17 and 18 are cut-away views of a variation of the head in first and second configurations, respectively.

[0044] Figure 19 is a cut-away view of a variation of the head.

[0045] Figure 20 is a cut-away view of a variation of the irrigation and aspiration device.

[0046] Figure 21 is a partially see-through view of a variation of the irrigation and aspiration device.

[0047] Figure 22 is a cut-away view of a variation of the aspiration component of the irrigation and aspiration device.

[0048] Figures 23 and 24 are isometric and side partial cut-away views of a variation of the irrigation and aspiration device.

[0049] Figure 25 and 26 are side and front views of the irrigation and aspiration device of Figures 23 and 24.

[0050] Figures 27 and 28 illustrate various methods for filling the irrigation and aspiration device with irrigant.

[0051] Figure 29 is a cut-away view of a variation of the irrigation and aspiration device.

[0052] Figure 30 is a partial cut-away view and partial schematic diagrams of a variation of the irrigation and aspiration device.

[0053] Figure 31 is partial cut-away view and partial schematic diagrams of a variation of the irrigation and aspiration device.

[0054] Figure 32 is partial cut-away view, partial see-through view and partial schematic diagrams of a variation of the irrigation and aspiration device.

[0055] Figure 33 illustrates a variation of the irrigation and aspiration device.

[0056] Figures 34a-c are isometric, top and side views, respectively, of a variation of a dual diaphragm pump.

[0057] Figures 35 through 37 illustrate a variation of a method of using a variation of the irrigation and aspiration device.

[0058] Figure 38 illustrates a variation of a method of using a variation of the irrigation and aspiration device.

[0059] Figures 39, 40, 41 and 44 are schematic diagrams of a variation of the irrigation and aspiration device in various configurations.

[0060] Figures 42 and 43 are schematic drawings of a variation of the first valve and the surrounding channels of Figure 41 in first and second configurations, respectively.

[0061] Figures 45 through 47 illustrate a distal portion of a variation of the irrigation and aspiration device showing the articulating neck in various configurations.

[0062] Figure 48 illustrates a variation of a method of using a variation of the irrigation and aspiration device with the articulating neck.

DETAILED DESCRIPTION

[0063] Figures 1 and 2 illustrate a cleaning device or system for irrigation and/or aspiration of biological tissues or fluids. The device can be used in a body cavity, such as the nasal cavity, the mouth and/or throat, the ear, the eye, a skin fold, the bellybutton, a wound, or combinations thereof. The device can be inserted into a natural body orifice (i.e., a normal physiological orifice, such as a nostril, mouth – including access to the throat, esophagus, stomach and lungs - ear canal, eye, naval, rectum, urethra, vagina, or adipose or fat fold), a wound, a surgical device (e.g., surgery port), or combinations thereof. The device can be configured to perform nasal aspiration and/or nasal irrigation alone, sequentially or simultaneously. Aspiration can include suctioning. The device can be configured to irrigate and suction concurrently. The device can have an automatically driven vacuum and a manually actuated irrigation, both of which can operate simultaneously.

[0064] The device can have a body. The body can encase a power source or supply. The body can be connected to an external power source (e.g., via a power cord). The body can have a fluid control system. The fluid control system can have a driving motor. The fluid control system can have a pump. The pump can be manual or automatic (e.g., AC or DC electrically powered). The pump can be or have a piston pump, a blower, a turbine, a fan, a diaphragm pump or combinations thereof. The motor can be part of the pump. The fluid control system can have valves that can be configured to control the flow of fluid within the fluid control system.

[0065] The outer wall as well as internal portions of the body can be made from a plastic, for example ABS, polycarbonate, or a combination thereof. The outer wall as well as internal portions of the body can be made by injection molding, for example by injection molding halves and assembling.

[0066] The body can be attached or integral with a neck. The neck can be attached or integral with a head. The neck can be attached to the body at a neck connector. The neck connector can be a screw, snap, press fit connector, or combinations thereof. The neck can be a flexible or rigid connection between the head and the body.

[0067] The head can be directly, or via the neck, attached or integral with the body. The head can be positioned at varying angles relative to the body. The head can articulate freely relative to the body (e.g., handle). The body can be held in the user's hand. The connections of the head to the body can be compliant and flexible so as the head can pivot and translate from the perimeter of the head (this is stated for exemplary purposes only, there are multiple mechanical solutions).

[0068] The neck can be articulatable (e.g., pivotable, otherwise rotatable, translatable). The neck can be freely articulatable, can articulate at fixed, stepped angles, or combinations thereof. For example, the neck can have gussets or ribs configured to allow the head to rotate with respect to the body.

[0069] The components within the neck can be configured to rotate with the neck. For example, as shown in Figure 2, an aspirant pressure line, atomizing channel (or atomization channel), and irrigant pressure line can be flexible and extendable. The irrigant channel (e.g., at the irrigant pressure line), atomization channel, and aspirant channel (e.g., at the aspirant pressure line) can each have a re-attachable division or split therein. The re-attachable division can connect in a male-female manner, such as a screw fit, snap fit, press fit, or combinations thereof. The re-attachable division can, for example, enable the head to be removed from the body while removing part of the channels with the head and while leaving the remaining portion of the channels attached to or integral with the body. The re-attachable division or split can also enable rotation and translation along the channels between the head and the body.

[0070] The body can have grip pads. The grip pads can have soft rubber. The grip pads can be attached and/or integral with the body. The grip pads can be ergonomically located about the body. The grip pads can be configured to be located at all or some of the locations where the user (e.g., the user's palm) naturally applies pressure to the body during use.

[0071] The body can have various colors, transparent, translucent, and/or opaque materials, and/or lights, for example for operational purposes and/or for entertainment of the user.

[0072] The device can have a power source. The power source can be stored completely or partially in a compartment, for example a battery compartment. The battery compartment can be in the body. The power source can have one or more electrical cells (e.g., one or more batteries). The power source can have, for example, four AA alkaline batteries in series. The power source can produce 6 volts and approximately 2,000 mAh. The power source can connect to an external supply of electricity (e.g., a 120 V electrical wall outlet). The battery compartment can be accessible from outside of the body through a battery compartment door. The battery compartment door can be removably attached to the body. The battery compartment door can be hingedly attached to the body.

[0073] The body can have a power light (e.g., LED).

[0074] The one or more pumps and valves can be in fluid communication with an aspirant pressure line, and/or an atomizing channel and/or an irrigant pressure line. The control can

be configured to manage which valves are open and closed, and/or how open and closed the valves are, and/or what pumps are on or off, and/or at what speed (e.g., flow rate and/or pressure) which pumps operate. The pumps and valves can create positive and/or negative pressures in the aspirant pressure line, and/or atomizing channel, and/or irrigant pressure line. The aspirant pressure line, and/or atomizing channel, and/or irrigant pressure line can have individual inflow and outflow sub-channels into the pumps and valves.

[0075] The device can have a control. The control can be configured to provide multiple functions. The control can enable user-induced, automated actuation of the device. For example, the control can have a dual function switch, or one or more multiple-function switches, or one or more single-function switches, or combinations thereof. The switch can have a button. The switch can be attached or integral with the body, head, neck, or combinations thereof.

[0076] The control can transmit power from the power source to the pumps and valves. The control can be configured to receive input from the one or more switches (e.g., the button). The control can control power delivery (e.g., electricity) from the power source to the pump and valves. The control can receive a first input, for example the sliding translation of the button or the pressing translation of the button. The control can receive a second input. for example the other of the sliding translation of the button or the pressing translation of the button that is not the first input. The first input can control the aspiration, for example whether aspiration is on or off and/or the intensity of the pressure and/or flow rate of aspiration. The second input can control the irrigation, for example whether irrigation is on or off and/or the intensity of the pressure and/or flow rate of the irrigation.

[0077] The switch can have a single sliding button. The switch can be operated by a single digit (i.e., finger or thumb). One or more switches can control the aspiration (i.e., suction) and irrigation with one digit (i.e., finger or thumb). The switch can be configured to receive multiple input signals (e.g., from the user). The switch can have one, two or more degrees of freedom. For example, the button can receive a pressing translation, as shown by arrow, and a sliding translation, as shown by arrows. The control, via the multiple input signals (e.g., pressing and sliding), can be configured to separately control (e.g., binary/two-state control (on/off) and/or variable control of the magnitude of power to gradually increase or decrease) the aspiration and the irrigation. For example, one input signal (e.g., sliding) can control the aspiration and another input signal (e.g., pressing) can control the irrigation. The sliding can be along the longitudinal axis of the body, head or neck. The pressing can be orthogonal to the sliding.

[0078] The switch can be bi-functional. The switch can have a rocker platform that can encase a variable speed switch. The switch can be moved from an off setting to a maximum speed (and/or on/off) setting by sliding the switch along the platform. The platform can be flush with, inside, or outside the device housing. The platform can be hinged at a first end and free at a second end. The platform can be resiliently pressed toward the remainder of the device, for example, over a balancing spring. Pressing the platform can manually actuate, or activate automatic actuation of, irrigation.

[0079] The pressing the pivoting switch housing can automatically actuate irrigation (i.e., spraying) and/or aspiration. For example, pressing the switch can trigger the control to allow pressure from the pump and valves to be directed to the irrigation channel (i.e., discharge tube) and consequently the atomization port (e.g., spray nozzle), for example via the exhaust (i.e., high pressure) side of the pump.

[0080] The device can have a first switch configured to control, for example via the pump and valves, pressure in the aspiration channel. The device can have a second switch configured to manually actuate a pump to deliver pressure to an irrigation channel and an atomization channel (i.e., spray mechanism), for example schematically analogous to a squirt-gun mechanism. The first switch can be activated by a first digit (e.g., the thumb). The second switch can be activated by a second digit (e.g., the index finger), for example schematically and/or ergonomically analogous to a squirt-gun trigger.

[0081] The control and/or pump can be manually (e.g., user-induced) or automatically (e.g., electrically) actuated and/or powered and/or otherwise controlled. The control, including the switch, can be simple and intuitive to use.

[0082] The head can have one or more irrigation ports. The irrigation ports can be configured to dispense or otherwise discharge an irrigation fluid. The irrigation port can be adjacent or within an atomizing port. The atomizing port can be configured to dispense or otherwise discharge the irrigation fluid in an atomized configuration, for example, by mixing the irrigation fluid (e.g., in a liquid state) with an atomizing gas. The atomization channel can have an input at an atomization reservoir or from an external source (e.g., an intake port open to the outside air).

[0083] The head can have a terminal end configured to be placed adjacent to, or inserted into, a biological orifice or surface to be irrigated and aspirated. For example, the terminal end of the head can be configured to fit into a nostril. The terminal end of the head can have a pointed conical, rounded conical, nippled, or waisted configuration or combinations thereof.

[0084] The body can be configured to be ergonomically held in a single hand. The body can have contours to fit the palm and fingers when grasped. With a filled irrigant reservoir and/or aspirant reservoir and in-body power source (e.g., containing one or more electrical cells), the device can weigh less than or equal to about 5.0 kg (11 lbs.), more narrowly less than about 2.0 kg (4.4 lbs.), for example about 0.45 kg (1.0 lbs.). The irrigant and/or aspirant reservoirs can be translucent and/or transparent, for example to allow a user to identify when to replace irrigant and/or empty aspirant, and/or to check cleanliness and/or operation of the device.

[0085] The irrigant and/or aspirant reservoirs can be cleanable, for example dishwasher safe (e.g., the ability to withstand about 15 minutes at least at about 50°C, or more narrowly at least about 75°C, without substantially noticeable deformation, deterioration, or other damage, and lack of substantial deterioration or other substantial damage from similarly extended exposure to water and typical dishwasher detergents).

[0086] The head can have a nozzle at or near the end of the head. The nozzle can be the tip of the head. The nozzle can have the irrigation and/or aspiration ports.

[0087] The aspiration channel (e.g., vacuum lumen) for suctioning can connect via the aspiration port (e.g., vacuum portal) of the nozzle on the main housing. The aspiration channel can lead to the aspirant reservoir (e.g., collection chamber) for aspirant (e.g., mucous) collection.

[0088] The device can have multiple, diverging aspiration channels, for example, to limit clogging. The aspiration channels can have minimal or no tight radius curvature (e.g., the aspiration channels can be substantially straight), for example to limit clogging. The aspiration channels can have removably attached filters.

[0089] The aspirant reservoir can be in the body and/or, neck, and/or head. The aspirant reservoir can be configured to receive aspirant through an aspiration channel and/or one or more aspiration ports. The aspirant reservoir can be integral or fixedly or removably attached to the remainder of the device. The aspirant reservoir can be a replaceable cartridge or ampoule. The aspirant reservoir can hold aspirant. The aspirant can include biological fluids and tissue and/or previous dispensed irrigant. The aspirant reservoir volume can be, for example, about 5 mL.

[0090] The body can have a cavity or recessed area in the housing for a removable irrigant reservoir. The body can have an integral or attached irrigant reservoir.

[0091] The irrigant reservoir can be in the body and/or, neck, and/or head. The irrigant reservoir can be configured to hold and dispense irrigant through an irrigation or irrigant

channel and/or one or more irrigation ports. The irrigant reservoir volume can be, for example, about 5 mL.

[0092] Flow from the irrigant reservoir can pass through an irrigant reservoir valve before entering the irrigant channel and/or irrigation port. The irrigant reservoir valve can be a check valve (i.e., substantially or completely preventing backflow into the irrigant reservoir). For example, the irrigant reservoir valve can be a ball valve, swing valve, clapper valve, umbrella valve, double check valve, duck bill valve, as shown, or combinations thereof.

[0093] The irrigant reservoir can be integral or fixedly or removably attached to the remainder of the device. The irrigant reservoir can hold irrigant. The irrigant reservoir can be a replaceable cartridge or ampoule. The irrigant reservoir can be disposable, replaceable, recyclable, or combinations thereof. The irrigant reservoir can be pre-filled with irrigant or ready for adding all or a component (e.g., water) of the irrigant. The irrigant reservoir can be divided into multiple sub-reservoirs. For example, one sub-reservoir can have salt and another irrigant reservoir can have water. The sub-reservoir contents can mix (e.g., creating saline solution) when the irrigant is dispensed.

[0094] The irrigant reservoir can be the same volume, a larger volume than, or a smaller volume than the aspirant reservoir. For example, the aspirant reservoir volume can be about 100 or less times larger than the irrigant reservoir volume, or more narrowly, about 20 or less times larger than the irrigant reservoir volume, or more narrowly, about 7 or less times larger than the irrigant reservoir volume, or more narrowly, about 3 or less times larger than the irrigant reservoir volume, or more narrowly about 1.5 or less times larger than the irrigant reservoir volume, for example the aspirant reservoir volume can be about 1.25 times the irrigant reservoir volume.

[0095] The irrigant reservoir can be a first color (e.g., blue), the aspirant reservoir can be the first color or a second color (e.g., yellow or red). The irrigant reservoir and/or aspirant reservoir can be transparent, translucent or opaque. The irrigant reservoir can seat into the device in a different configuration than the aspirant reservoir. For example, the irrigant reservoir, aspirant reservoir and the remainder of the device can be configured so as to not be able to insert the irrigant reservoir in the device in place of the aspirant reservoir and/or vice versa.

[0096] The irrigation fluid or irrigant can have or be water, saline solution, zinc solution (e.g., zinc sulfate solution), alcohol, anesthetic agent, analgesic agent, antipyretic agent, anti-inflammatory agent such as a non-steroidal anti-inflammatory agent (e.g., ibuprofen,

aspirin, salicylic acid, COX02 inhibitor, COX-3 inhibitor), acetaminophen, live attenuated flu vaccine, antihistamine (e.g., azelastin hydrocholoride), corticosteroid (e.g., fluticasone propionate), topical decongestant (oxymetazoline hydrochloride), vitamin (e.g. vitamin c, ascorbic acid), nicotine, other therapeutic or diagnostic medication, or combinations thereof.

[0097] The irrigant can combine with an atomizing gas at the atomizing port. The atomizing port can be a nozzle configured to atomize the irrigant.

[0098] The atomizing gas can have or be air, carbon dioxide, oxygen, nitrogen, nitrous oxide, another anesthetic, or combinations thereof.

[0099] Figure 3 illustrates a variation of the head with irrigant and aspirant flow. Irrigant pressure, as shown by arrow, can be applied to the irrigant reservoir. The irrigant pressure can force the irrigant from the irrigant reservoir through the irrigation channel.

[0100] Atomizing pressure, as shown by arrows, can be applied to the atomizing channel. The atomizing pressure can for the atomizing gas through the atomizing channel.

[0101] The nozzle can be configured to mix the irrigant and the atomizing gas at the atomizing port. The nozzle can be configured to nebulize or atomize the irrigant with the atomizing gas as the irrigant flows out of the atomizing port. The atomized irrigant can flow away from the nozzle.

[0102] The atomized irrigant can include particles having a diameter from about 0.1 μm (0.004 mil) to about 100 μm (4 mil) upon exit from the atomization port. The atomized irrigant particles can have a high mobility and can substantially uniformly coat, adhere and interact with the target site, tissues, and fluids.

[0103] The irrigant can be delivered as one or more unatomized streams (i.e., shower-like) without the mixing with an atomizing gas. For example, the device can have no atomization channel.

[0104] The nozzle can be configured to deliver the irrigant in a stream or flood (e.g., not atomized), for example by having no atomization port (e.g., or other atomization elements).

[0105] A negative aspirant pressure can be applied to the aspirant reservoir. The aspirant can flow, as shown by arrows, through the aspiration ports and into the aspirant reservoir. The aspirant can collect in the aspiration reservoir.

[0106] The irrigant port and atomizing port can be radially central to the terminal end of the head. The aspirant ports can be radially off-center or otherwise away from the irrigant port and atomizing port on the head.

[0107] There is an inner lumen (irrigation lumen) of the nozzle that is either central or eccentric which delivers a spray of saline upon manual/automatic actuation, much like a water gun inside of a suction device. This portion of the nozzle corresponds to the aspiration portal of the nozzle base on the main housing.

[0108] The control, pumps, and heads can be configured to provide various irrigation flow characteristics. For example, the device can be configured to flood (e.g., unbroken, unhollow stream, for example substantially cylindrical stream), and/or atomize, and/or conical (e.g., hollow or unhollow conical stream) irrigation characteristics. The flow characteristics can be automatically or manually adjusted. The nozzle or head can be manually replaced with a differently configured nozzle or head to change the irrigation characteristics.

[0109] Figures 4 and 5 illustrate that the aspiration port can have an inflow check (i.e., one-way) valve for inflow configured to substantially or completely prevent backflow of aspirant from the aspiration channel or reservoir. The inflow check valve can be or have a ball valve, swing valve, clapper valve, umbrella valve, double check valve, duck bill valve, as shown, or combinations thereof. The inflow check valve can be integral or fixedly or removably attached to the aspiration port and/or the aspiration channel and/or the aspirant reservoir. The aspiration port can be radially central to the terminal end of the head. The irrigation channel can be radially off-center or otherwise away from the aspirant port on the head.

[0110] The head can have an attachment ring on the inside or outside of the head. The attachment ring can be configured to attach to the neck and/or the body.

[0111] Figure 6 illustrates that the aspiration channel or aspirant reservoir can have a exhaust trap. The exhaust trap can have a trap valve. The trap valve can be a resilient flap. The trap valve can be a check valve configured to release excessive pressure from the aspirant reservoir and/or aspirant channel into the exhaust trap. For example, the excessive pressure in the aspirant reservoir or aspiration channel can force fluid (i.e., aspirant or gas in the aspirant reservoir or aspiration channel) between the trap valve and a relatively rigid trap flange. The contact area of the trap valve and the trap flange can be a trap intake seal.

[0112] The trap flange, and/or aspiration channel can direct incoming flow of aspirant from the aspiration port adjacent to the trap intake seal so that a low pressure is naturally produced on the aspiration channel-side and/or aspirant reservoir-side of the trap intake seal during aspirant flow from the aspiration port into the aspirant reservoir.

[0113] The exhaust trap can drain through an exhaust trap port to the outside of the device or to a separate overflow exhaust reservoir (not shown). The exhaust trap port can be open or can have a manual or automatic pressure release valve, for example a check valve. The device can be configured to drain aspirant (e.g., passively or under applied pressure) from the aspirant reservoir through the exhaust trap and the exhaust trap port.

[0114] The exhaust trap can have a trap overflow seal. The trap overflow seal can be a check valve configured to release excessive pressure from the exhaust trap into the aspiration channel and/or aspirant reservoir. The trap overflow seal can be made from a portion of the trap valve and the outer wall of the aspiration channel or aspirant reservoir.

[0115] The aspiration valve can be integral with or attached to an aspiration valve gasket. The aspiration valve and/or aspiration valve gasket can be snap-fit (as shown, around an extending ring or collar configuration), press-fit, attached with an adhesive, or otherwise attached to the aspiration port.

[0116] The irrigation channel can be located in the irrigant reservoir.

[0117] Figures 7 and 8 illustrate that the irrigation channel can be concentric with the atomizing channel. The irrigation channel can be in an irrigation conduit. The atomizing channel can be in an atomizing conduit. The irrigation conduit can be concentric with the atomizing conduit. The irrigation channel can be inside the atomizing conduit.

[0118] The aspiration valve can be a check valve concentric with the atomizing port and/or irrigation port. The aspiration valve can form the aspiration seal against the aspiration and/or irrigation conduit.

[0119] Figure 9 illustrates that the irrigation conduit can have first, second, third and more atomizing vanes. The vanes can be configured to radially extend from the center of the irrigation conduit. The vanes can longitudinally extend along all or part of the irrigation conduit. The vanes and the atomizing conduit can form first, second, third and more atomizing sub-channels within the atomizing channel. The atomizing sub-channels can be venturis. The edges of the vanes can be sharpened, for example to induce turbulent flow around the edges of the vanes.

[0120] The concentric tube design (i.e., with the irrigation channel internal to a concentric aspiration channel roximal to the respective ports) can have the outer tube (e.g., atomization channel) be shorter than the inner tube (e.g., irrigation channel). The difference in length between the atomization and irrigation channels can allow for the irrgiant to be atomized when pressurized irrigant passes up the center tube (e.g., irrigation

channel) which can be filled from the reservoir, and pressurized air can pass through the outer tube (e.g., aspiration channel).

[0121] The concentric tube design can be inverted with respect to the configuration described supra. For example, the irrigant reservoir can be inverted and the atomization channel can be central to the concentric irrigation channel. The nozzle can be "flooded" to spray the irrigant by filling the outer tube (i.e., irrigant channel) with pressurized irrigant and the inner tube (e.g., atomization channel) with pressurized air or other gas. For example, infants can be laying down and receive drops of irrigant and toddlers can be sitting up and receive atomized irrigant.

[0122] Figures 10 and 11 illustrate that the irrigation conduit can be integral with or attached to the head. The head can have an irrigation conduit port. The irrigation conduit port can receive the irrigation conduit.

[0123] Figures 10 through 13 illustrate that the head can have first, second and more atomizing channels. The atomizing channels can be on the outer surface of the head. The atomizing channels can have venturis.

[0124] The irrigation channel in the head can extend from the irrigation conduit port to the irrigation port (not shown, but can be located inside the head and adjacent to or in the atomizing port). The first and second aspiration channels can merge. The first and second aspiration channels can merge adjacent to the irrigation port. The first and second aspiration channels can merge adjacent to the aspiration port.

[0125] The atomization gas can flow from outside the head, for example from outside the device or from an atomization conduit within, attached, or adjacent to the irrigation conduit.

[0126] Figure 14 illustrates that the irrigation port can be located adjacent to the aspiration port. The irrigation port can be completely or partially surrounded by the aspiration port. The aspiration port can be completely or partially surrounded by the irrigation port. The irrigation conduit can be inside the aspiration conduit. The irrigation conduit can be non-concentric with the aspiration conduit. The irrigation port can be flush on one side of the aspiration conduit.

Figure 15 illustrates that the head can have one or more ports (representing the irrigation and/or aspiration and/or atomization ports). The head can be configured as a bulb. Non-skewed alignment along a longitudinal axis of the head presents a secondary challenge to the user and/or patient. Figure 16 illustrates that the terminal end of the head can be configured as a nipple. The terminal end of the head can be bulged or waisted. The

terminal end of the head can have a larger radius distal to the port, for example, to prevent overinsertion of the head into a natural body orifice.

[0127] The terminal end of the head can be configured to make a positive seal with the irrigation and aspiration site (e.g., the nostril). The head can seal to the irrigation and aspiration site analogous to a ball and socket joint and/or similar to nested tubes. The terminal end of the head can be rotationally symmetric about a longitudinal axis of the head. The rotational alignment can be decoupled from the sealing functionality, for example allowing one more degree of freedom for the user.

[0128] The terminal end of the head, or all of the head, can be made from and/or covered or coated with, a compliant material such as silicone rubber or foam. The terminal end of the head or all of the head can be compliant, for example, to permit sealing to differently-shaped nostrils. The terminal end of the head, or all of the head can be sufficiently rigid to not deform against the negative pressure of the aspiration.

[0129] The head can have an irrigation component and an aspiration component. Figure 17 illustrates that the irrigation component can have a piston within a cylinder. The piston can have one or more gaskets. The gaskets can fluidly seal between the piston and the cylinder. The piston can have a nozzle at a terminal end of the piston. The piston can be integral with or attached to the atomizing channel and the irrigant channel.

[0130] The irrigation component can have a resilient valve or seal, for example an elastomeric seal. The elastomeric seal can fluidly separate the nozzle from the outside of the head (e.g., during use, the nasal cavity, for example), for example when the device is in a retracted (e.g., not irrigating) configuration.

[0131] The cylinder can be volumetrically rigid or compliant (e.g., if desired to expand to accommodate excessive pressures). The cylinder can have a cylinder top and a cylinder bottom. The cylinder top can be the volume fluid sealed by the piston from the volume of the cylinder bottom. The atomizing channel can have one or more cylinder ports into the cylinder top and/or cylinder bottom. The cylinder port can have an active or passive valve.

[0132] Figure 18 illustrates that high pressure fluid (e.g., atomizing gas) can be introduced under an atomizing pressure, as shown by arrows, into the atomizing channel. The atomizing pressure can enter the cylinder bottom or top (for exemplary purposes, shown as cylinder bottom). Force from the atomizing pressure and/or another force (e.g., from a motor not shown) can translate, as shown by arrows, the piston toward the elastomeric seal.

[0133] The nozzle can be translated toward and out the elastomeric seal. The translation of the nozzle can cause the seal to rotate open, as shown by arrows. The rotated open

elastomeric seal can fluidly seal against the nozzle, for example directly or via one or more gaskets.

[0134] The atomization port can translate out of the elastomeric seal, as shown by arrow. The irrigant can be delivered via the irrigation port, for example with the flow exiting the atomizing port unobstructed by the elastomeric seal.

[0135] Instead of, or in combination with, a piston-deployed irrigation component, the device can have a reciprocating and/or syringe-deployed irrigation component, similar to the piston-deployed irrigation component shown in Figures 17 and 18.

[0136] Figure 19 illustrates that the head can have a single combined port for aspiration and irrigation. The aspiration can occur concurrently or subsequent to the irrigation. The aspiration channel can be configured to direct the suction pressure of the aspiration adjacent to the perimeter of the combined port. The irrigation channel can be configured to direct the irrigation to the center of the combined port.

[0137] The irrigation channel can have an irrigation channel lining. The irrigation channel lining can actively (e.g., can be movable, such as an electro-active polymer skin) or passively (e.g., by the shape of the channel lining) focus the exiting stream of irrigant. The irrigation channel lining can form a venturi in the irrigation channel. The irrigation channel lining can be integral with, or fixedly or removably attached to the irrigation channel.

[0138] The irrigation channel can have an irrigation channel break. The irrigation channel break can be configured to act as a venturi. The irrigation channel break can be configured to increase turbulence in the flow of the irrigant through the irrigation channel.

[0139] Figure 20 illustrates that the irrigation component can have an atomizing reservoir or atomizing channel (labeled as a reservoir for exemplary purposes) partially or completely circumferentially surrounding the irrigant reservoir or irrigant channel. The atomizing reservoir can be embedded in the wall of the irrigation component, for example in the wall or case of the irrigant reservoir. The irrigation component can be resiliently flexible. The aspirant and irrigant can be delivered by squeezing the irrigation component.

[0140] The irrigation conduit can be molded into the wall of the irrigation component.

[0141] The irrigation channel can form a venturi. The irrigation channel can have an irrigation channel diameter. The irrigation channel diameter can be the minimum internal diameter of the irrigation channel. The irrigation channel diameter can be less than about 1 cm (0.4 in.), more narrowly less than about 2 mm (0.8 in.) , for example about 0.7 mm (0.03 in.).

[0142] Figure 21 illustrates that the aspiration reservoir can be a resilient container, such as an elastomeric bulb. The aspiration reservoir can have an exhaust conduit. The exhaust conduit can be in fluid communication with the aspiration reservoir. The exhaust conduit can have an exhaust valve and an exhaust port. The exhaust valve can be an check valve configured to flow away from the aspiration reservoir.

[0143] The nozzle can be integral with or removably attached to the aspiration reservoir. The aspiration port nozzle or the aspiration reservoir can have an aspiration valve. The aspiration valve can be a check valve, for example any check valve stated herein such as an umbrella check valve.

[0144] The irrigation component can have an irrigation trigger. The irrigation trigger can be operated by a single digit. When the irrigation trigger is pulled, the irrigation component can dispense irrigant.

[0145] When the aspiration reservoir is squeezed, the aspiration valve can close and the exhaust valve can open. The aspirant in the aspiration reservoir can be forced out the exhaust conduit and the exhaust port. The exhaust valve can be a duckbill valve. When the previously-squeezed aspiration reservoir is relaxed, the exhaust valve can close and the aspiration valve can open. Suction can then result at the aspiration port and aspirant can be drawn into the aspiration reservoir.

[0146] Figure 22 illustrates that the aspiration valve can be a duckbill valve (the irrigation component is not shown). The aspiration component and/or the device can have a base. The base can be configured to enable the device to stand on a flat surface (e.g., a table), for example, keeping the aspiration and atomization and/or irrigation ports off the flat surface.

[0147] Figures 23 and 24 illustrate that the irrigation port can be centrally located within a substantially circular aspiration port. The aspiration port and the irrigation port can be at the outer surface of the head and/or the aspiration port and/or the irrigation port can be recessed within the head.

[0148] The head can have the aspiration reservoir and the irrigation reservoir. The aspiration reservoir can be in direct fluid communication with the aspiration port.

[0149] The device can have one or more valves configured to control the irrigation delivery pressure and/or the aspiration suction pressure. The valves can be actuated by one or more buttons, such as a press-button, as shown. The valves can be in fluid communication with the pump and the irrigant pressure line, aspirant pressure line and atomizing channel, and an exhaust port and intake port. In closed positions, the valves can bleed or release pressure to the exhaust port and/or suction through the intake port. In

opened positions, the valves can delivery positive pressure from the pump to the irrigant pressure line and the atomizing channel, and negative pressure from the pump to the aspirant pressure line.

[0150] The pump can be a piston and/or diaphragm pump, such as the dual diaphragm pump, as shown in Figures 23 and 24.

[0151] The aspirant reservoir and/or irrigant reservoir can be in the head. The aspirant reservoir and/or irrigant reservoir can be in direct fluid communication (e.g., not via a separate channel) with the aspiration port and/or irrigation port, respectively. The lack of a separate channel connecting the aspirant and/or irrigation reservoir and the aspiration port and/or irrigation port, respectively, can obviate the need to clean the separate channel.

[0152] The device can have a portable power source, such as batteries, as shown in Figures 23 and 24. For example, the device can have 1, 2, 3 or 4 AA-sized cells. The cells can be inserted through a battery door in the bottom of the device.

[0153] The pump can be connected to a control or controller, such as a motor. The control can have a microprocessor configured to regulate the motor speed to control irrigant delivery pressure and/or aspirant suction pressure. The aspirant suction pressure can be, for example, from about 80 mm Hg (1.5 psi) to about 120 mm Hg (2.32 psi). The control can receive an input from the button. The microprocessor can analyze the button position to control the motor speed and/or valve position.

[0154] Figures 25 and 26 illustrate that the grip pads can be ergonomically placed on the front and back of the body. The grip pads can have ridges or texturing. The grip pads can be made from metal, soft plastic or rubber. The head can be opaque, transparent and/or translucent. The head can be removably attached to the neck and/or the neck can be removably attached to the remainder of the body.

[0155] Figure 27 illustrates that the irrigant can be refilled. The irrigant reservoir can have an irrigant reservoir seal against the outer wall of the irrigant reservoir. For example, the irrigant reservoir seal can be plastic. The irrigant reservoir seal can be self sealing and/or manually controlled to open and close.

[0156] An external irrigant container can have fresh irrigant. The external irrigant container can have a container spout configured to insert into the irrigant reservoir through the irrigant reservoir seal. The external irrigant container can be advanced into the irrigant reservoir seal, as shown by arrow. The contents of the external irrigant container can then be deposited into the irrigant reservoir, for example by squeezing the external irrigant container and/or by opening a pressure release port (not shown) on the external irrigant

container. The irrigant in the external irrigant container can then be transferred into the irrigant reservoir. The external irrigant container can then be removed from the irrigant reservoir seal and the irrigant reservoir seal can close.

[0157] Figure 28 illustrates that the head can have a cartridge receptacle configured to removably attach to an irrigant cartridge. The cartridge receptacle can have ports, hooks, latches, pegs, or combinations thereof that can removably attach to the same on the irrigant cartridge. When the irrigant cartridge is not attached, the cartridge receptacle can define a void substantially equivalent to the configuration of the irrigant cartridge.

[0158] The irrigant cartridge can have the irrigant reservoir that can contain irrigant. The irrigant cartridge can be inserted into the irrigant receptacle, as shown by arrow. The irrigant cartridge can have one or more ports (not shown) that can engage the irrigant pressure line and/or irrigant channel when the irrigant cartridge is attached to the cartridge receptacle. The ports on the irrigant cartridge can be closed or covered, for example by adhered aluminum foil when the irrigant cartridge is not in the cartridge receptacle. For example, the cartridge receptacle can have one or more fangs or tubes configured to pierce the irrigant cartridge (e.g., through a foil or seal) and be in fluid communication with the interior of the irrigant cartridge and pressurize or depressurize the irrigant cartridge and/or withdraw irrigant from the irrigant cartridge.

[0159] A first irrigant cartridge can be removed from the irrigant receptacle and replaced with a second irrigant cartridge, for example when the first irrigant cartridge is empty.

[0160] In another variation, when the irrigant reservoir is empty and/or the aspirant reservoir is full or otherwise in need of emptying or cleaning, the entire head can be removed from the neck and replaced with a second head containing more irrigant in the irrigant reservoir. Likewise, the aspirant reservoir can be removed (similar to the sole removal of the irrigant cartridge). The head and/or irrigant reservoir and/or aspirant reservoir and/or the device can be washed, for example, by hand and/or in a dishwasher. The body and/or the device can be waterproof.

[0161] Figure 29 illustrates that the aspiration reservoir can be in a resilient vacuum bulb. The vacuum bulb can be elastomeric. The aspiration reservoir can be in fluid communication with the irrigation reservoir, for example, via an irrigation-aspiration port. The irrigation-aspiration port is configured to be away from the aspirant fluid level in the aspirant reservoir.

[0162] An irrigation-aspiration valve can be in fluid communication with the aspiration reservoir and the irrigation reservoir. The irrigation-aspiration valve can be a check valve.

The irrigation-aspiration valve can be a valve permitting flow only from the aspiration reservoir to the irrigation reservoir and preventing flow from the irrigation reservoir to the aspiration reservoir.

[0163] The aspiration valve can be a one-way check valve permitting flow into the aspiration reservoir.

[0164] The irrigation reservoir can be in an irrigation container. The irrigation container can be rigid, for example a plastic bottle. The irrigation container can be integral with or removably attachable to the remainder of the device at an attachable reservoir joint. The atomization fluid reservoir can be the top of the irrigation reservoir, above the level of the irrigant.

[0165] The base can extend from the reservoir container. The base can be wider than the widest portion of the remainder of the device.

[0166] Squeezing the vacuum bulb can atomize and eject irrigant from the atomization port. For example, when the vacuum bulb is squeezed, the irrigation-aspiration valve can open and the irrigation reservoir can be pressurized via the irrigation-aspiration port. The increased pressure in the irrigation reservoir can cause the irrigant to flow through the irrigation channel. The increased pressure in the irrigation reservoir can also force gas in the irrigation reservoir (e.g., above the irrigant) through the atomization channel.

[0167] Relaxing the previously squeezed irrigation-aspiration valve can suction aspirant into the aspiration reservoir. For example, the irrigation-aspiration valve can close. The negative pressure in the aspiration reservoir can draw in aspirant by opening the aspiration seal in the aspiration port.

[0168] Figure 30 illustrates that one or more covers can be configured to fit over the aspiration and/or irrigation and/or atomization ports.

[0169] The device can have a manually or automatically controllable dual exhaust valve. The dual exhaust valve can be passive or active. The dual exhaust valve can regulate excessive fluid pressure from the aspiration reservoir and/or the irrigant reservoir to an exhaust conduit. The excessive fluid pressure can exit the exhaust conduit as an exhaust flow, shown by arrow.

[0170] An irrigation valve can regulate flow from the irrigant reservoir to the irrigation port. The irrigation valve can be configured to prevent the irrigant from exiting the irrigation port at an excessive pressure. The velocity of the irrigant flow stream can be prevented from exiting the device at an excessive velocity.

[0171] Figures 31 and 32 illustrate that the aspirant reservoir can be in an inner irrigant reservoir wall. The irrigant reservoir can be between an inner irrigant reservoir wall and an outer irrigant reservoir wall. The inner irrigant reservoir wall and the outer irrigant reservoir wall can be rigid, resilient or deformable.

[0172] The device can have an atomization intake port on the outside surface of the device. The atomization intake port can be in fluid communication with the atomization fluid reservoir. The atomization intake port can have a check valve configured to allow one-way flow from the atomization intake port to the atomization fluid reservoir.

[0173] The atomization valve can regulate flow between the irrigant reservoir to the atomization channel. The atomization channel can have a venturi configuration adjacent to the irrigation port. The venturi can atomize the irrigant and/or increase the speed of the atomization gas.

[0174] The irrigant valve can regulate flow between the irrigant reservoir and the irrigant channel. The irrigant valve can be a check valve. The irrigant valve can prevent flow from the irrigant channel to the irrigant reservoir. The irrigant valve can permit substantially free flow from the irrigant reservoir to the irrigant channel. The irrigant valve can restrict the flow from the irrigant reservoir to the irrigant channel except under high pressure differentials, for example a pressure differential greater than about 25 mmHg (0.5 psi), more narrowly a pressure differential greater than about 100 mmHg (2 psi), more narrowly a pressure differential greater than about 260 mmHg (5 psi), more narrowly a pressure differential greater than about a pressure differential greater than about 760 mmHg (14.7 psi), for example for a pressure differential greater than about 1600 mmHg (30 psi) .

[0175] An irrigant intake port can be in fluid communication with the irrigant reservoir. The irrigant intake port can have a check valve configured to allow one-way flow from the irrigant intake port to the irrigant reservoir. The irrigant reservoir can be filled by introducing irrigant through the irrigant intake port.

[0176] The aspiration channel can have a valve transition zone. The valve transition zone can be configured as a smooth transition from the inner wall of the aspiration channel to the inner wall of the aspirant valve.

[0177] An exhaust valve can regulate flow between the aspirant reservoir and the exhaust port. The exhaust port can be covered and uncovered by the user (e.g., by a digit, such as the thumb) during use. The exhaust can flow from the aspirant reservoir and out the exhaust port, as shown by arrow.

[0178] The device shown in Figures 31 and 32 can be squeezed to deliver the irrigant. Releasing the device from a squeezed configuration can aspirate.

[0179] Figure 32 shows that the irrigant and atomization fluid can be mixed a mixing valve. The mixing valve can be upstream from the atomization port.

[0180] Figure 33 illustrates that the device can have a body that can be attached to the head with a lead. The lead can carry the irrigant pressure line and/or irrigant channel, aspirant pressure line and/or aspirant channel, atomization channel or combinations thereof. The lead can be flexible. The lead can be retractable into the body, for example with a spring-loaded retraction mechanism. The lead can be coiled. The head can have a removably attached aspirant reservoir and/or irrigant reservoir (not shown separately).

[0181] The body can have a flat base. The body can be attached to a surface such as a flat surface (e.g., floor, table, crib). for example with screws, nails, brads, bolts or combinations thereof. The body can be weighted with ballast and/or have a clamp (e.g., to stabilize).

[0182] Figures 34a through 34c illustrate that the fluid control and pump can have a motor attached to a first and/or second diaphragm. The pump can be a piston or diaphragm pump (i.e., a membrane pump, positive displacement pump). The pump can be a boxer pump, having at least two oppositely-oriented oscillating shafts, rods, or membranes. The pump can be or have a compressed gas (e.g., air, carbon dioxide, nitrogen) canister that can be configured to controllably release the compressed gas.

[0183] The pump can have two doubled-up diaphragms. The pump can be driven by a motor that can be driven by the power source. The device can produce a maximum irrigant volumetric flow rate of at least about 9,000 cc/m, more narrowly at least about 12,000 cc/m, yet more narrowly at least about 15,000 cc/m. The pump and other features disclosed in U.S. Patent No. 6,520,931, which is incorporated by reference herein in its entirety, can be used herein.

[0184] The pump can have one or more blowers, turbines, fans, diaphragms, bellows, or combinations thereof. The pump can be manually and/or electrically powered. The pump can be attached to an AC or DC-driven motor.

[0185] Figure 35 illustrates that a user can ergonomically hold the body in a single hand. The user can rest a digit, such as the thumb, on the button. The palm and/or other fingers can substantially or completely rest on the grip pads.

[0186] Figure 36 illustrates that the thumb can slidably translate the button, as shown by arrow. The slidable translation of the button can control irrigation or aspiration. As shown for example, sliding the button can actuate the device to create a suction resulting in

aspirant flow, as shown by arrow. The distance the button is slidably translated can directly correlate to the pressure of the aspiration or irrigation.

[0187] Figure 37 illustrates that the thumb can slidably translate, as shown by arrow, and concurrently depressingly translate, as shown by arrow, the button. The depressing translation can control the other of the irrigation or aspiration not controlled by the sliding translation. Sliding and depressing the button can actuate the device to create a suction resulting in aspirant flow, as shown by arrow, and resulting in a pressured fluid delivery resulting in the irrigant flow, as shown by arrow.

[0188] Figure 38 illustrates that the device, such as the variation shown in Figure 21, can be actuated to irrigate by rotating a trigger on a hinge, for example with one or more digits (e.g., the forefinger and/or middle finger). The aspirant reservoir can be completely or partially emptied by compressing, as shown by arrows, the aspirant reservoir, for example with the thumb, ring finger, pinky and palm. The aspirant can be drawn into the aspiration port by releasing the compressed aspirant reservoir.

[0189] Variations of the device, such as those shown in Figures 29 through 32, can be actuated by squeezing (e.g., for irrigation) and releasing (e.g., for aspiration) all or part of a resilient portion of the device, such as a bulb.

[0190] Figure 39 illustrates that the pump can draw air from the aspirant reservoir. The resulting vacuum can draw aspirant flow, as shown by arrows, through the aspiration ports. The irrigant pressure line can have an excess flow port. The excess flow port can bleed excess pressure out of the irrigant pressure line as exhaust flow.

[0191] The device can have a first valve in a controlled exhaust line in fluid communication with the irrigant pressure line. The first valve can be actuated by a button. The button can be in a position configured to produce aspiration and no irrigation. All or part of the exhaust pressure from the pump can flow out of the device as exhaust flow, as shown by arrows. All or part of the exhaust pressure from the pump can flow throw the atomization channel and out the atomization port. The flow through the atomization port, as shown by arrows, can, for example, prevent aspirant from passively flowing into the atomization port. The irrigation pressure line can be significantly smaller than the controlled exhaust line. For example, no or unsubstantial flow can be generated in the irrigant pressure line while the controlled exhaust line is open.

[0192] Figure 40 illustrates that the button can be translated, as shown by arrow, to a configuration to produce aspiration and irrigation. The button can directly (as shown) or indirectly (e.g., via a control mechanism such as a valve attached to a servomotor) close the

controlled exhaust line. The flow can be the same as shown in Figure 31 except that substantial positive pressure can be routed through the irrigant pressure line. The irrigant can be forced through the irrigant channel, into the atomization port, mixed with the atomization gas, and sprayed out as atomized irrigant. Excessive pressure in the irrigant pressure line can be released as exhaust flow, as shown by arrow.

[0193] The device can be configured to prevent the irrigant from the irrigant reservoir from flowing solely from the application of pressure in the aspirant pressure line or aspirant channel. For example, the irrigant reservoir can be locked closed (e.g., preventing any irrigant from exiting the irrigant reservoir) by a locking valve (e.g., piston or syringe) when the device is configured to not irrigate (e.g., the irrigation control is set to "off"). When the device is configured to not irrigate, excess pressure from the aspirant pressure line and/or aspirant channel and/or the negative pressure side of the pump can be exhausted out of the device.

[0194] Figure 41illustrates that the device can have a first valve and/or a second valve. The first valve can be between the pump and the atomization channel and/or irrigant pressure line and an exhaust port. The second valve can be between the pump and the aspirant pressure line and an intake port. The first and second valves can be in the same housing or separate housings. The valves can act as switches for routing the air pressure to and from the pump. The button and valve spring can control the position of the valve channel.

[0195] Figure 42 illustrates that the first valve can be in a first configuration to direct the flow from the pump to the exhaust port and to obstruct flow from the pump to the atomization channel and/or irrigant pressure line. The button can be up and the valve spring can be expanded. Flow from the pump to the exhaust port can flow through the valve channel. Flow from the pump to the atomization channel and/or irrigant pressure line can be blocked by the first valve. The irrigant delivery pressure can be shut off completely or partially.

[0196] Figure 43 illustrates that the first valve can be in a second configuration to direct the flow from the pump to the atomization channel and to obstruct flow from the pump to the exhaust port. The button can be down and the valve spring can be compressed. Flow from the pump to the atomization channel and/or irrigant pressure line can flow through the valve channel. Flow from the pump to the exhaust port can be blocked by the first valve. The irrigant delivery pressure can be turned on completely or partially. The irrigant

delivery pressure can be, for example, from about 80 mm Hg (1.5 psi) to about 120 mm Hg (2.32 psi).

[0197] The second valve can have multiple configurations, similar to the first and second configurations shown for the first valve in Figures 42 and 43. For example, the second valve can have a first configuration to direct flow to the pump from the aspirant pressure line or to the pump from the intake port.

[0198] The first valve and/or the second valve can be manually or automatically controlled. The first and/or second valves can be bimodal (e.g., on or off positions only), multimodal (e.g., fixed finite valve settings), analog (e.g., substantially infinite variability of valve settings), or a combination thereof.

[0199] Figure 44 illustrates that the device can have a first pump and a second pump. The first pump and/or second pump can be manual or automatic (e.g., driven by an electric motor). For example the first pump can be automatic and the second pump can be manual, spring-loaded piston pump with a one-way valve, as shown. The first pump can provide aspirant suction pressure to the aspirant pressure line. The outgoing pressure from the first pump can be exhausted through the exhaust port.

[0200] The second pump can be in the irrigant channel. The second pump can pressurize the irrigant in the irrigant channel. The second pump can be pumped, as shown by arrow, for example by hand (e.g., with a thumb on a button). The second pump can be actuated by a thumb on a button on the body of the device. The irrigant can be atomized, as shown, upon exiting the atomization port. The irrigant can be delivered from the nozzle in a non-atomized stream or spray.

[0201] The pumps can have bellows.

[0202] The first pump can produce a different or the same flow rate and/or pressure as the second pump.

[0203] Figure 45 illustrates that the head can have a longitudinal head axis. The body can have a longitudinal body axis aligned with the head-end of the body. The head axis can be aligned with the body axis, for example, when the head is in a relaxed configuration and/or when the neck is in a relaxed configuration.

[0204] Figure 46 illustrates that the head can be rotated to a non-zero and positive head angle. The head angle can be the angle from the body axis to the head axis. The head angle between the head axis and the body axis can be from about -180° to about +180° (e.g., the head can have about 360° of rotational motion in one plane), for example about +35°, or 0°, or -35° (e.g., the head can have about 70° of rotational motion in one plane).

The neck can be configured to deform to the rotated head angle. The neck can resiliently reset to a preset head angle (e.g., 0°) when a rotating force on the head is removed.

[0205] Figure 47 illustrates that the head can be rotated to a negative head angle.

[0206] Figure 48 illustrates that the head can rotate, as shown by arrow, around the body. For example, the head axis can rotate around the body axis. The neck can rotate the head around the body.

[0207] The oscillations or vibrations of the device (e.g., due to pump motors, reciprocating solenoids, piezoelectric transducers) can be dampened. Actuators, pumps, valves and other moving parts can be mounted to the body, neck or head using dampers, such as soft rubber washers. Excessive pressure and pump exhausts can be muffled, for example using a restricting plate in an exhaust conduit or port. The walls of the device can be thickened and made from layered and/or laminated materials. The walls of the device can be otherwise sound-proofed. Moving parts in the device can be dynamically balanced, for example such that all support forces sum to zero at any given instant and/or the device can have active noise cancellation. Motors (e.g., in the pumps) can have counterbalances. Multiple motors can be configured to oppose dynamic forces.

[0208] Any of the valves herein can be flow diodes, such as check valves. Any of the valves herein can be ball valve, swing valve, clapper valve, umbrella valve, double check valve, duck bill valve, or combinations thereof.

[0209] The device can be configured at full power to aspirate, for example, up to about 20,000 cc/min. (1,220 in^3/min.) of air with no flow restriction. The device can be configured to at full power to produce an aspiration suction with no flow, for example, up to about 100 mmHg (2 psi). The device can be configured at full power to irrigate up to about 1.5 cc/min. (9.2 in^3/min.) of irrigant with no flow restriction.

[0210] The device can be configured to be portable. For example, the device can be unattached to any external devices (e.g., a wall or floor-mounted outlet or source for power, pressure, irrigant, or the aspirant reservoir).

[0211] The device can be configured to be handheld. For example, the device can weigh less than about 5.0 kg (11 lbs.), more narrowly less than about 2.0 kg (4.4 lbs.), more narrowly less than about 1.0 kg (2.2 lbs.). The device can have a total maximum diameter less than about 41 cm (16 in.), more narrowly less than about 30 cm (12 in.), yet more narrowly less than about 25 cm (10 in.).

[0212] The device can be used to deliver therapeutic drugs, and/or saline, and/or diagnostic agents, and/or antiseptic agents. The device can be used to delivery drugs to the lungs.

[0213] The device can have one, two or more buttons, rocker switches, or other elements to control the aspirant suction pressure and/or irrigant delivery pressure. The buttons (or other elements) can be used to activate electronics (e.g., the pump motor, microprocessor), valves, manually pump, or combinations thereof.

[0214] The terms aspiration and aspirant are used interchangeably herein when used as descriptors for elements (e.g., aspiration reservoir and aspirant reservoir). The terms irrigation and irrigant are used interchangeably herein when used as descriptors for elements. The terms atomizing and atomization are used interchangeably herein when used as descriptors for elements.

[0215] Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

CLAIMS

We claim:

1. A portable, handheld device for irrigating with an irrigant and aspirating biological tissue and/or secretions comprising:

a body;

a head connected to the body;

a first port in the head, the first port configured to deliver an irrigant to outside of the head;

a second port in the head, the second port configured to receive an aspirant from outside of the head; and

wherein the head comprises an aspirant reservoir in direct fluid communication with the second port; and

a fluid control system comprising a pump, wherein the fluid control system is configured to control an irrigation delivery pressure of the irrigant outside of the head.

2. The device of Claim 1, wherein the head is articulatably connected to the body.

3. The device of Claim 1, wherein the aspirant reservoir is removably attachable to the remainder of the head.

4. The device of Claim 3, wherein the aspirant reservoir is dishwasher safe.

5. The device of Claim 1, wherein the head is articulatable within the head.

6. The device of Claim 1, wherein the head further comprises an irrigant reservoir comprising the irrigant.

7. The device of Claim 6, wherein the irrigant reservoir is removable from the head.

8. The device of Claim 6, wherein the irrigant reservoir is configured to be refilled while in the device with the irrigant from an external source.

9. The device of Claim 1, wherein the head is configured with a larger radius distal to the first port and the second port to prevent overinsertion of the head into a natural body orifice.

10. The device of Claim 1, wherein the fluid control system is configured to control an aspirant suction pressure of the aspirant into the head.

11. The device of Claim 10, wherein the fluid control system is configured to simultaneously irrigate and aspirate.

12. The device of Claim 10, wherein the fluid control system is electronically driven.

13. The device of Claim 10, further comprising a manual control configured to control the fluid control system.

14. The device of Claim 10, wherein the fluid control system comprises a second valve configured to control the aspiration suction pressure.

15. The device of Claim 1, wherein the fluid control system comprises a first valve configured to control the irrigation delivery pressure.

16. The device of Claim 1, wherein the pump comprises a diaphragm pump.

17. The device of Claim 16, wherein the diaphragm pump comprises a dual diaphragm pump.

18. The device of Claim 1, wherein the pump comprises a piston.

19. The device of Claim 1, wherein the fluid control system comprises a first motor.

20. The device of Claim 1, wherein the body comprises a power source.

21. The device of Claim 1, wherein the head is removably attachable to the body.

22. A method for a user to irrigating and aspirating a natural body orifice comprising:

holding an entire device in a hand of the user, wherein the device is portable;

simultaneously irrigating at an irrigation pressure inside the nose with a device and aspirating at an aspiration pressure inside the nose with the device, wherein the device comprises a body and a head connected to the body, an irrigant reservoir, an aspirant reservoir, a first port in the head in fluid communication with the irrigant reservoir, and a second port in the head in direct fluid communication with the aspirant reservoir; and

wherein irrigating comprises delivering an irrigant from the irrigant reservoir, through the first port and into the natural body orifice with an irrigation pressure, and

wherein aspirating comprises receiving an aspirant from the natural body orifice, through the second port and directly into the aspirant reservoir with an aspiration pressure.

23. The method of Claim 22, further comprising articulating the head with respect to the body.

24. The method of Claim 22, wherein the simultaneously irrigating and aspirating comprises varying the irrigation pressure between non-zero irrigation pressures.

25. The method of Claim 22, wherein the simultaneously irrigating and aspirating comprises varying the aspirating pressure between non-zero aspiration pressures.

26. The method of Claim 22, further comprising electronically controlling the irrigation pressure and the aspiration pressure.

27. The method of Claim 22, further comprising storing in the device the irrigant.

28. The method of Claim 22, further comprising storing in the device the aspirated aspirant.

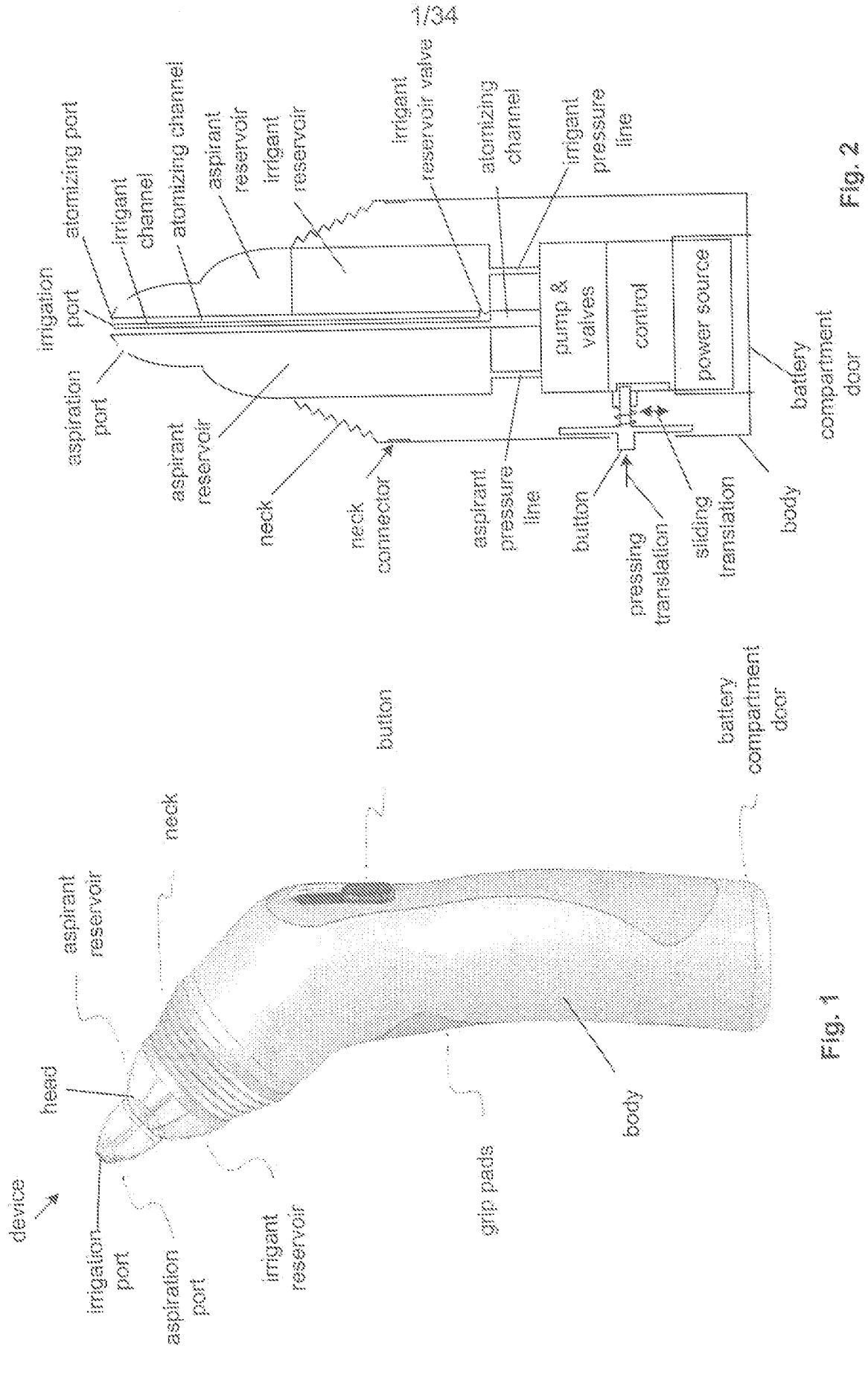
device
irrigation port
aspiration port
irrigant reservoir
grip pads
head
aspirant reservoir
neck
button
body
battery compartment door
irrigation port
atomizing port
irrigant channel
atomizing channel
aspirant reservoir
irrigant reservoir
irrigant reservoir valve
atomizing channel
irrigant pressure line
aspiration port
aspirant reservoir
neck
neck connector
aspirant pressure line
pump & valves
control
power source
battery compartment door
button
pressing translation
sliding translation
body

Fig. 1

Fig. 2

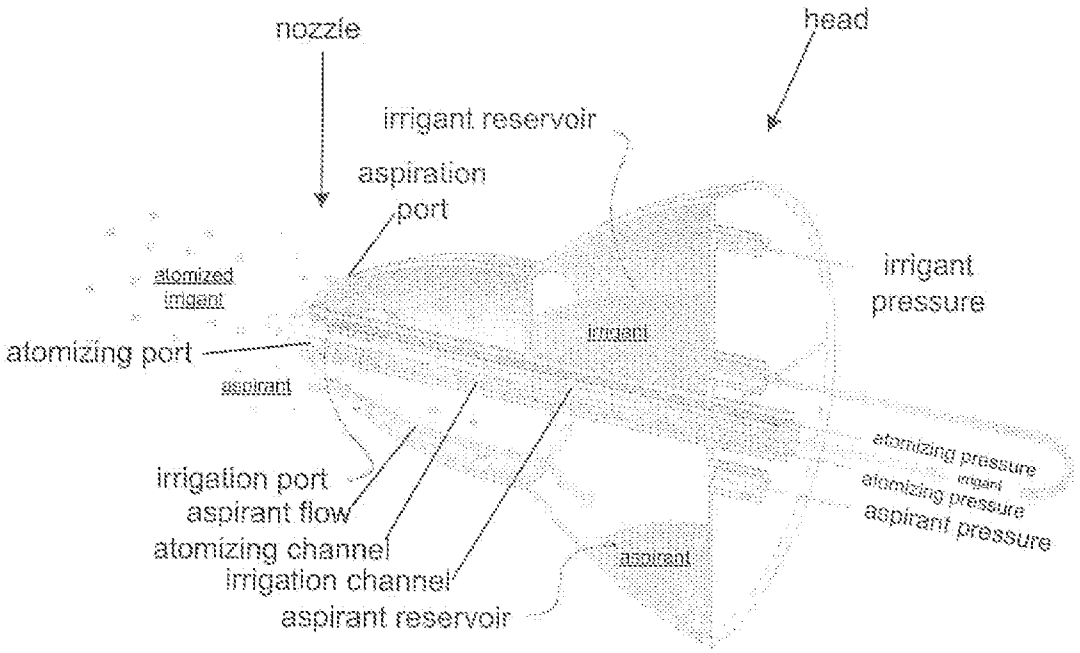
nozzle
head
irrigant reservoir
aspiration port
atomized irrigant
irrigant pressure
atomizing port
irrigant
aspirant
atomizing pressure irrigant
atomizing pressure aspirant pressure
irrigation port
aspirant flow
atomizing channel
irrigation channel
aspirant
aspirant reservoir

Fig. 3

duck bill valve
aspiration channel
aspiration port
irrigation port
irrigation channel
attachment ring

Fig. 5

head
duck bill valve
aspiration channel
aspiration port
irrigation port
irrigation channel
attachment ring

Fig. 4

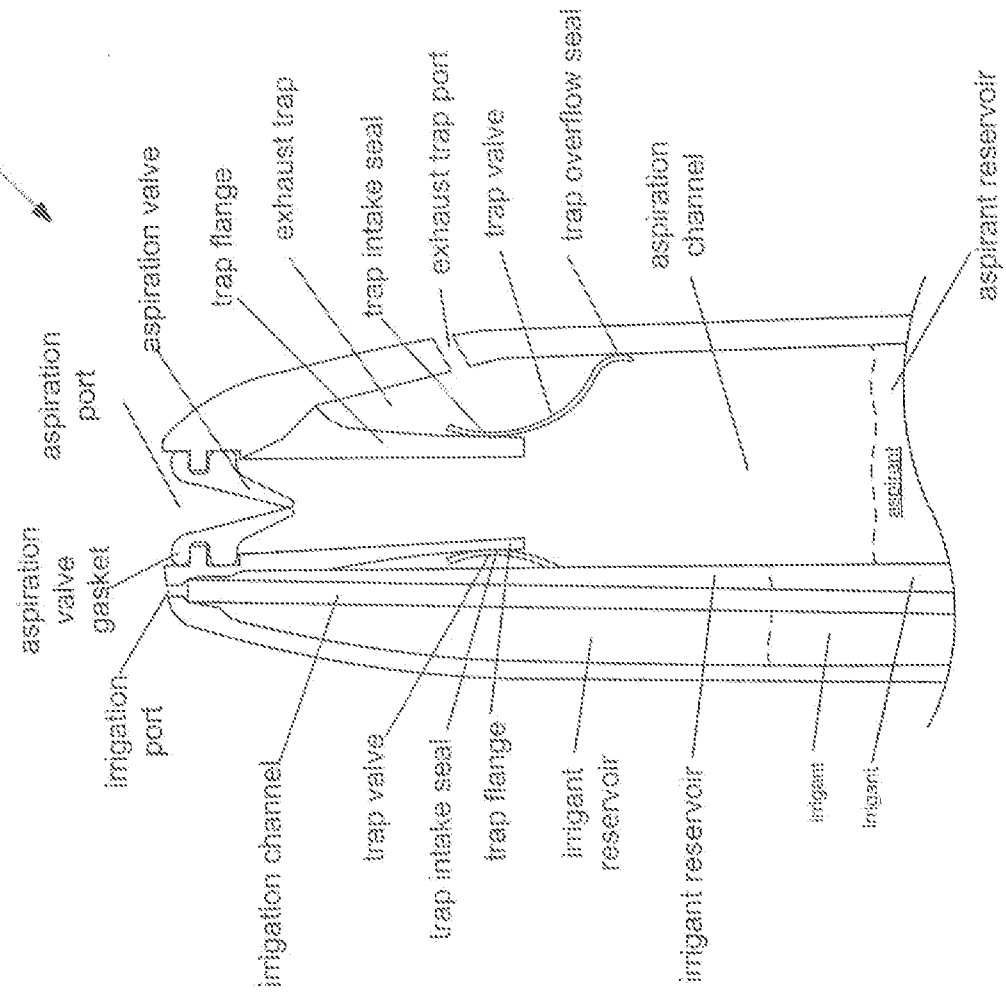
head
aspiration port
aspiration valve
trap flange
exhaust trap
trap intake seal
exhaust trap port
trap valve
trap overflow seal
aspiration channel
aspirant reservoir
aspiration valve gasket
irrigation port
irrigation channel
trap valve
trap intake seal
trap flange
irrigant reservoir
irrigant reservoir
irrigant
irrigant
aspirant

Fig. 6

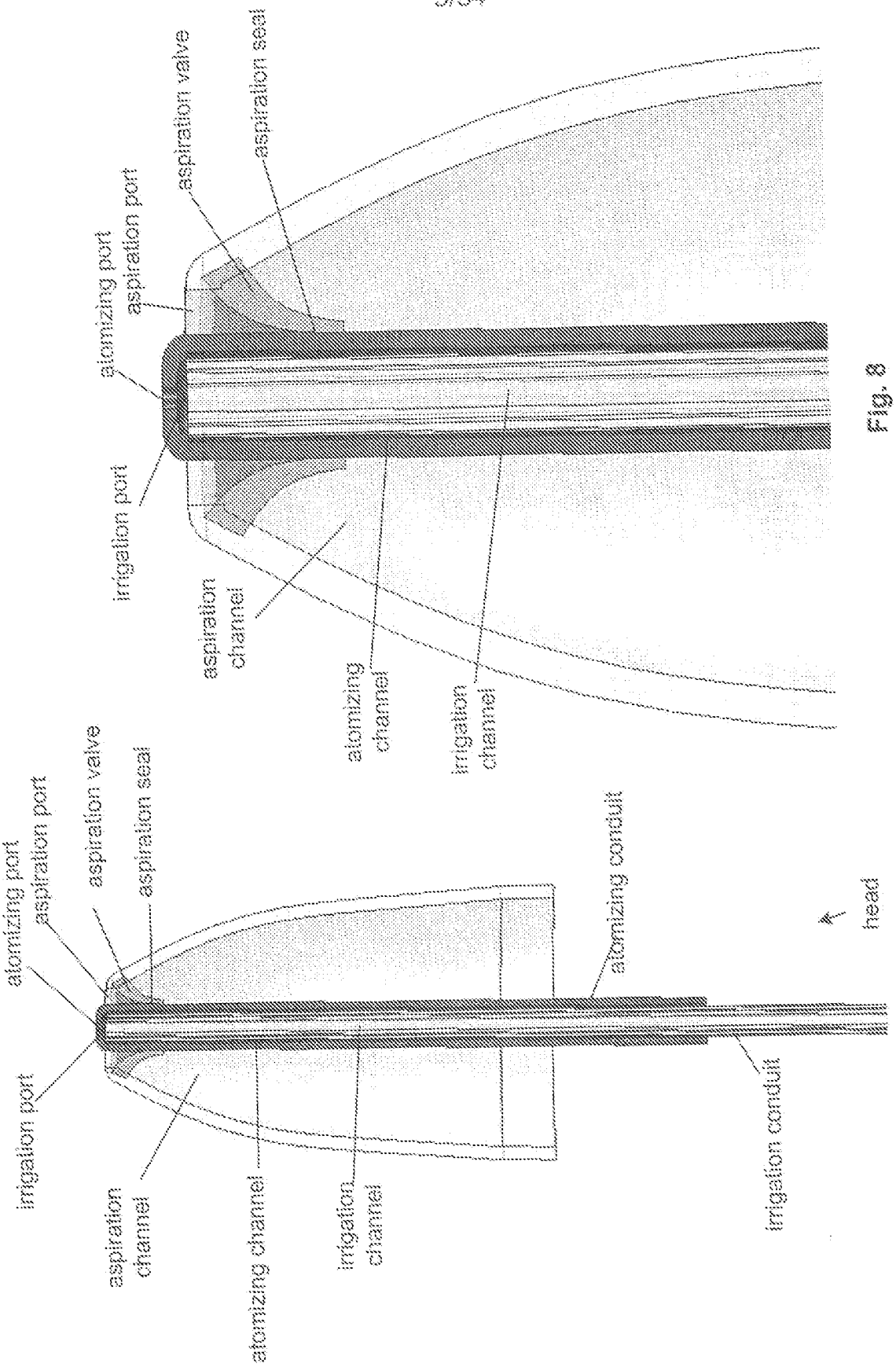
irrigation port
atomizing port
aspiration port
aspiration valve
aspiration seal
aspiration channel
atomizing channel
irrigation channel
atomizing conduit
irrigation conduit
head
irrigation port
atomizing port
aspiration port
aspiration valve
aspiration seal
aspiration channel
atomizing channel
irrigation channel
head

Fig. 7

Fig. 8

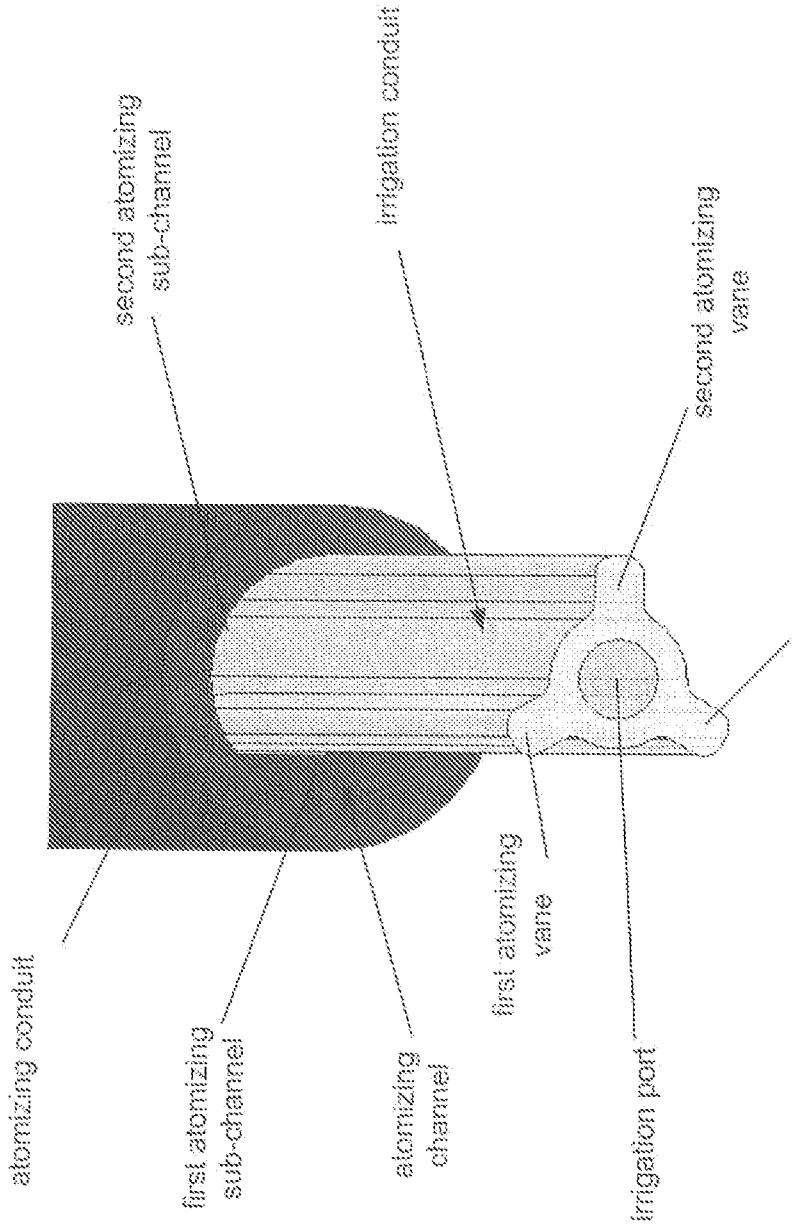
second atomizing sub-channel
irrigation conduit
second atomizing vane
third atomizing vane
atomizing conduit
first atomizing sub-channel
atomizing channel
first atomizing vane
irrigation port

Fig. 9

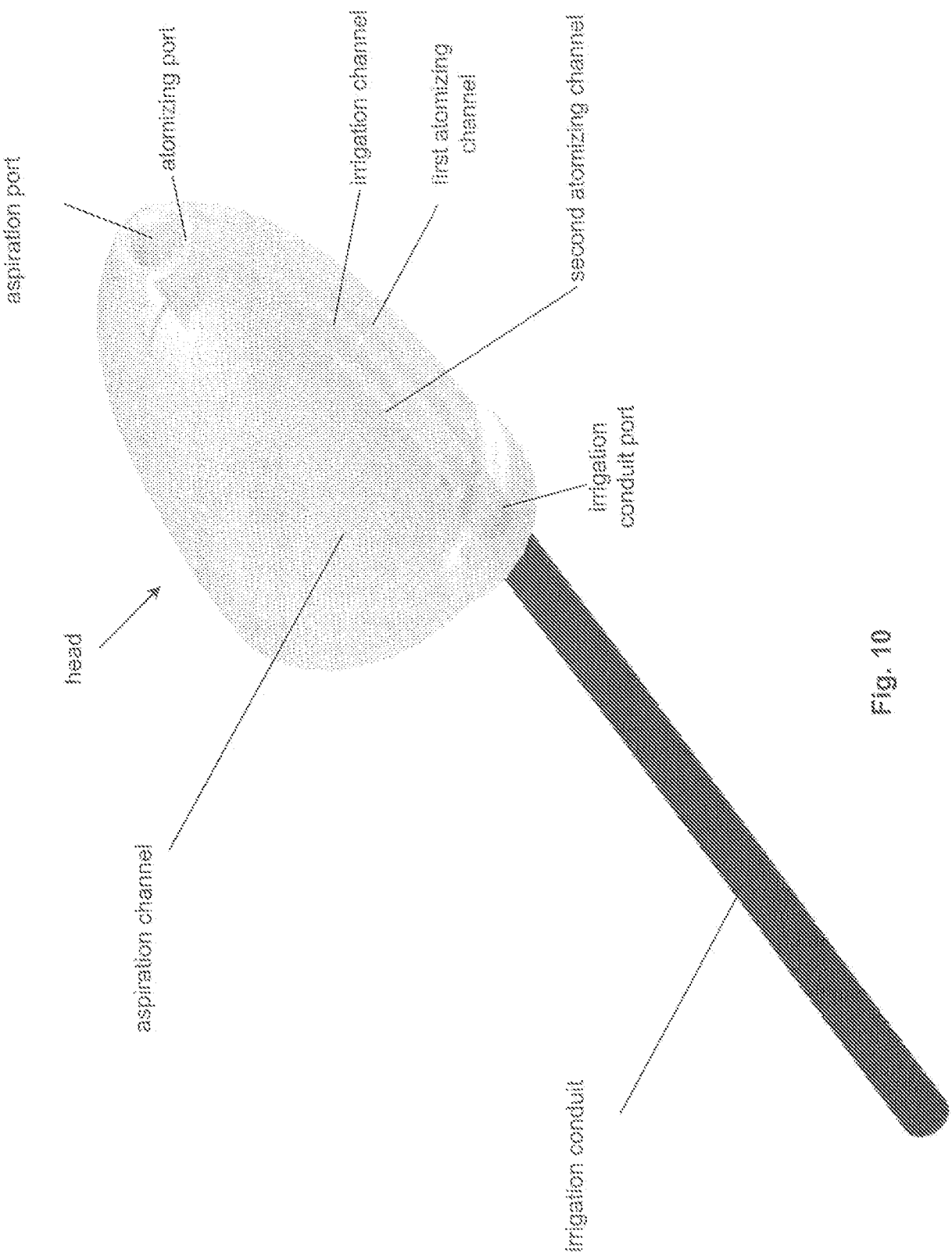
aspiration port
atomizing port
irrigation channel
first atomizing channel
second atomizing channel
irrigation conduit port
head
aspiration channel
irrigation conduit

Fig. 10

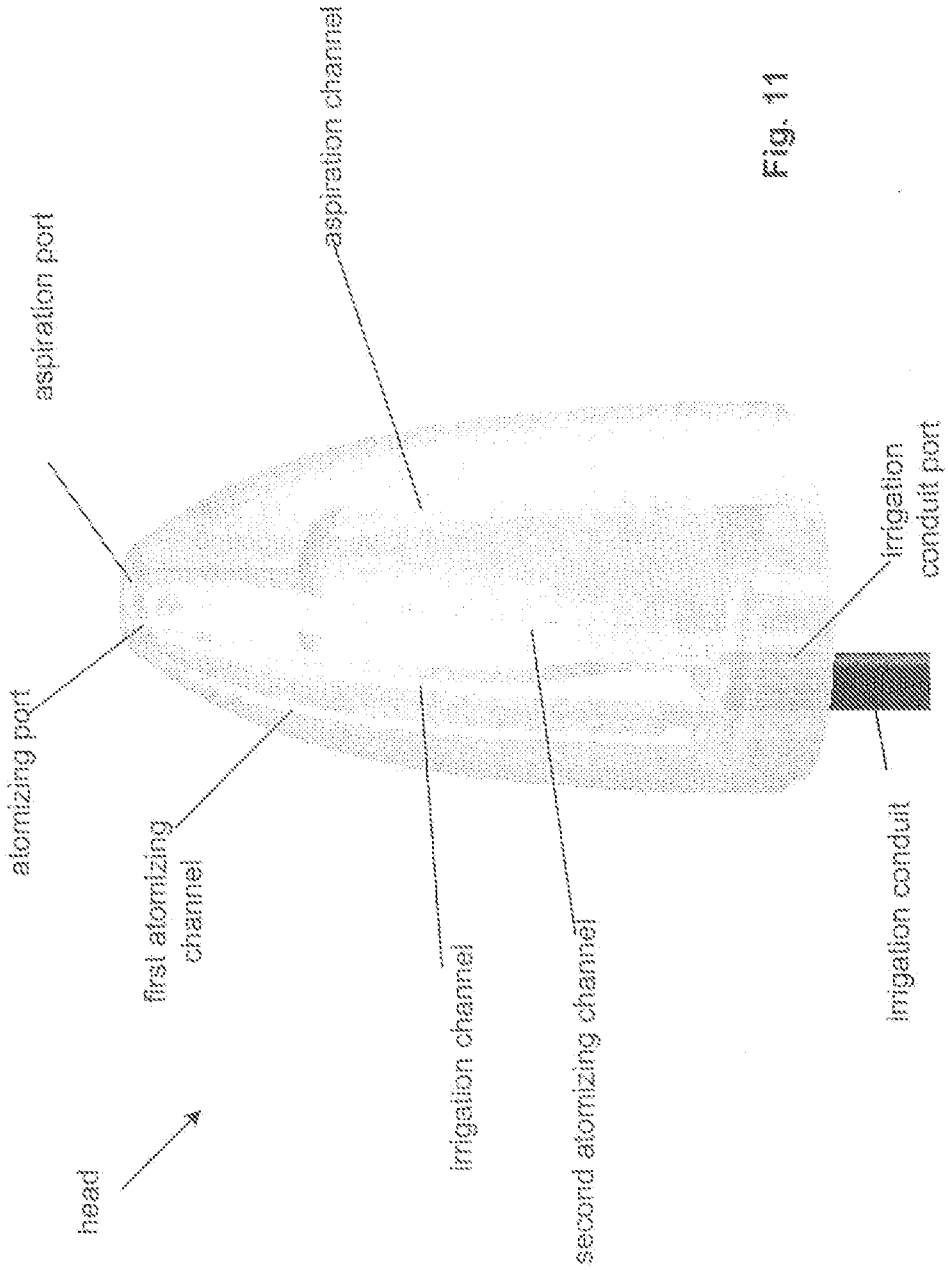
aspiration port
aspiration channel
atomizing port
first atomizing channel
irrigation channel
second atomizing channel
irrigation conduit port
irrigation conduit
head

Fig. 11

aspiration port
atomizing port
second atomizing channel
irrigation channel
first atomizing channel
aspiration channel
head

Fig. 13

atomizing port
first atomizing channel
irrigation channel
irrigation conduit port
aspiration port
head
aspiration channel

Fig. 12

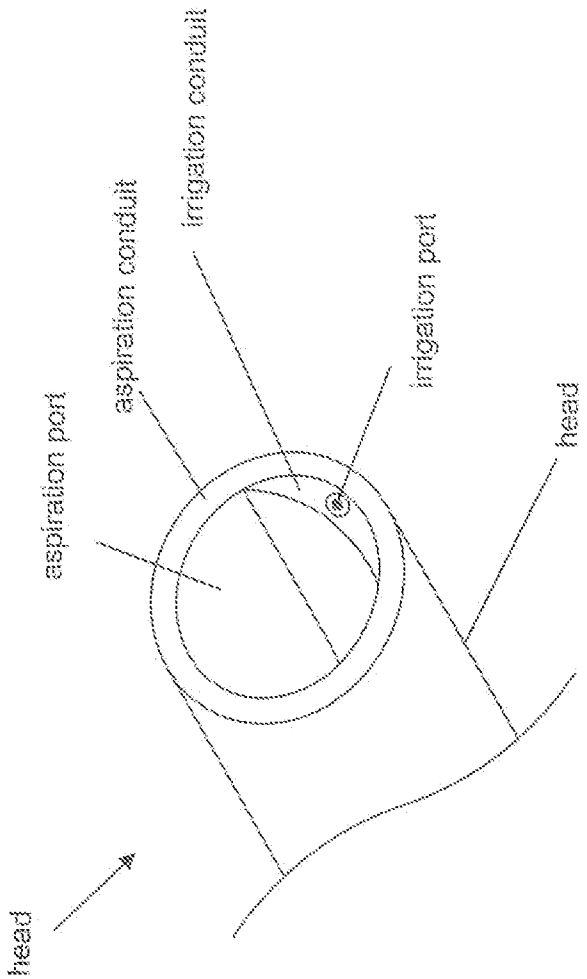
head
aspiration port
aspiration conduit
irrigation conduit
irrigation port
head

Fig. 14

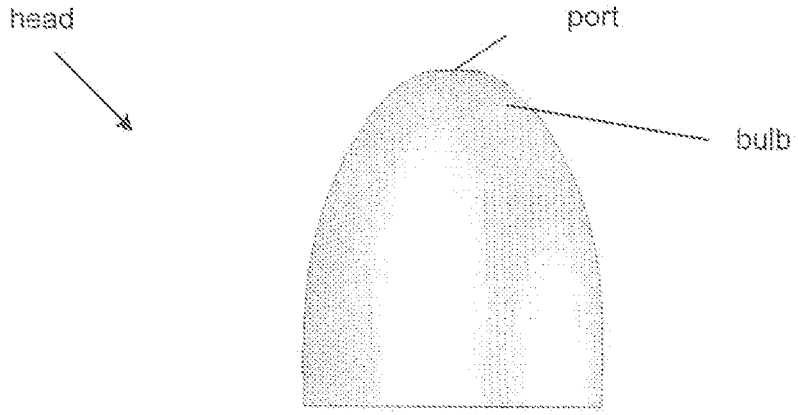

Fig. 15

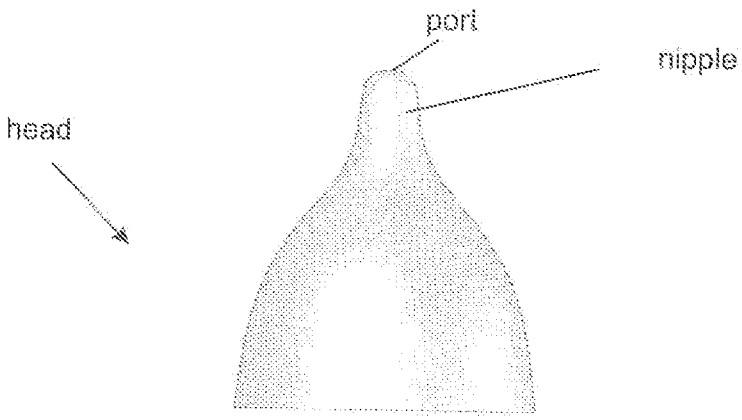

Fig. 16

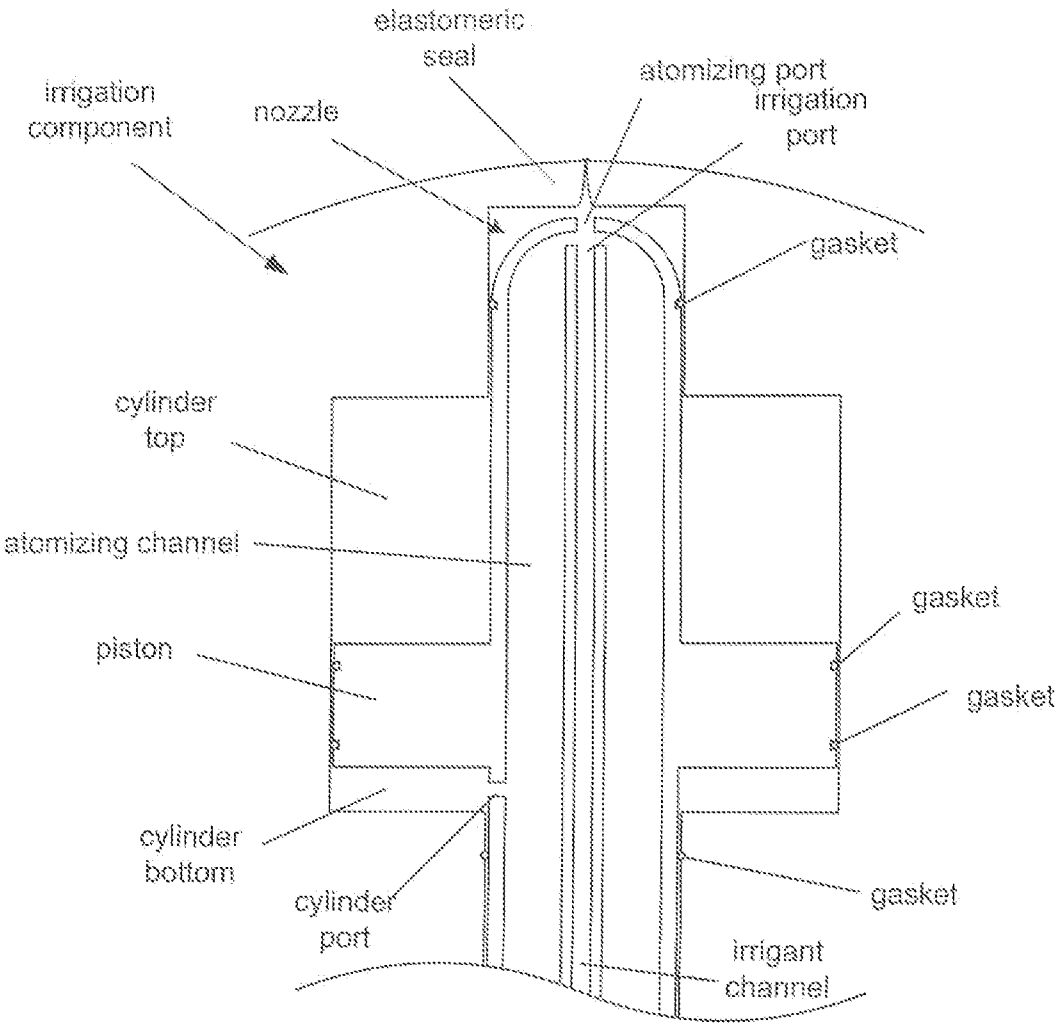
elastomeric seal
atomizing port
irrigation port
irrigation component
nozzle
gasket
cylinder top
atomizing channel
gasket
piston
gasket
cylinder bottom
gasket
cylinder port
irrigant channel

Fig. 17

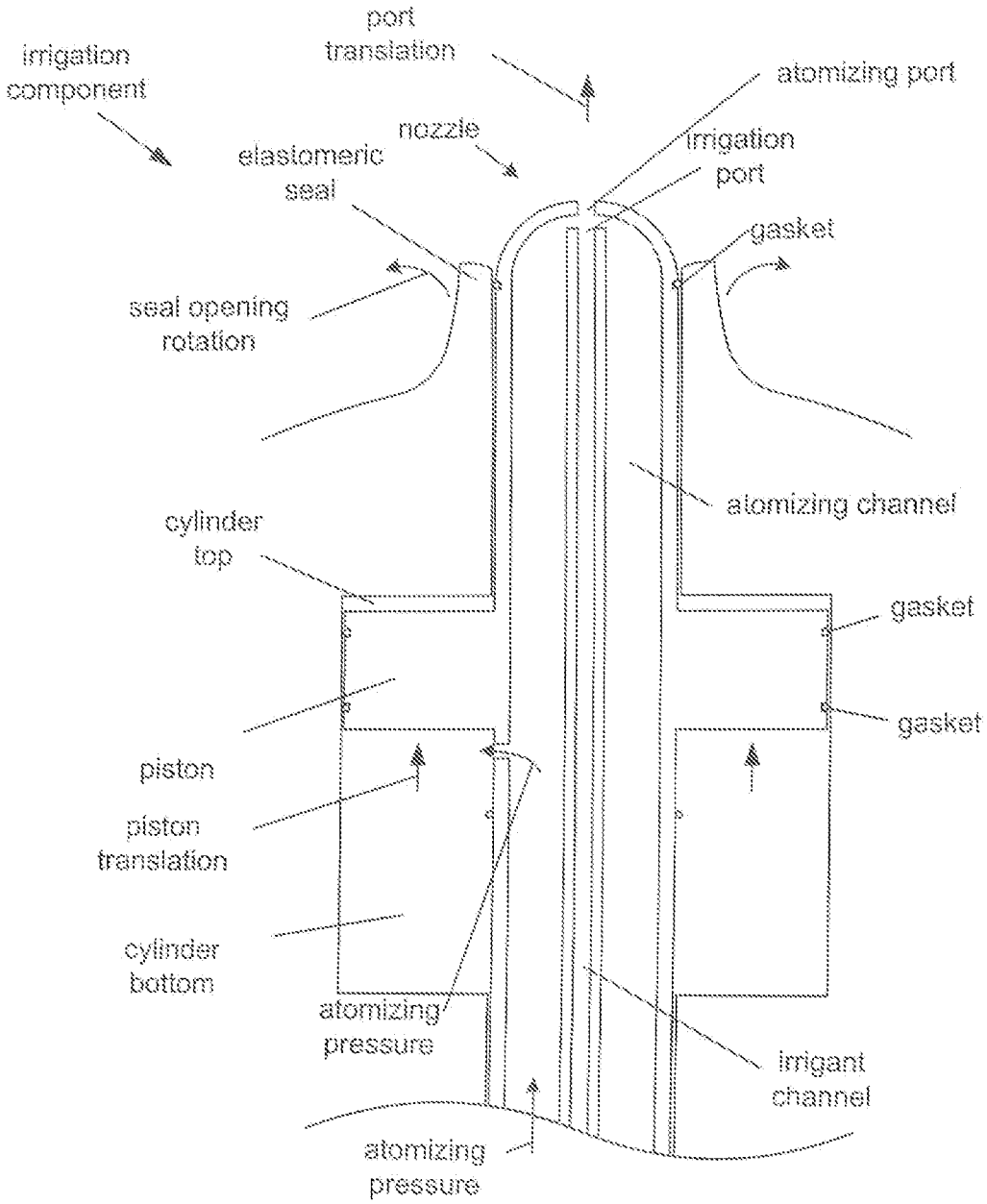
irrigation component
port translation
atomizing port
nozzle
elastomeric seal
irrigation port
gasket
seal opening rotation
atomizing channel
cylinder top
gasket
gasket
piston
piston translation
cylinder bottom
atomizing pressure
irrigant channel
atomizing pressure

Fig. 18

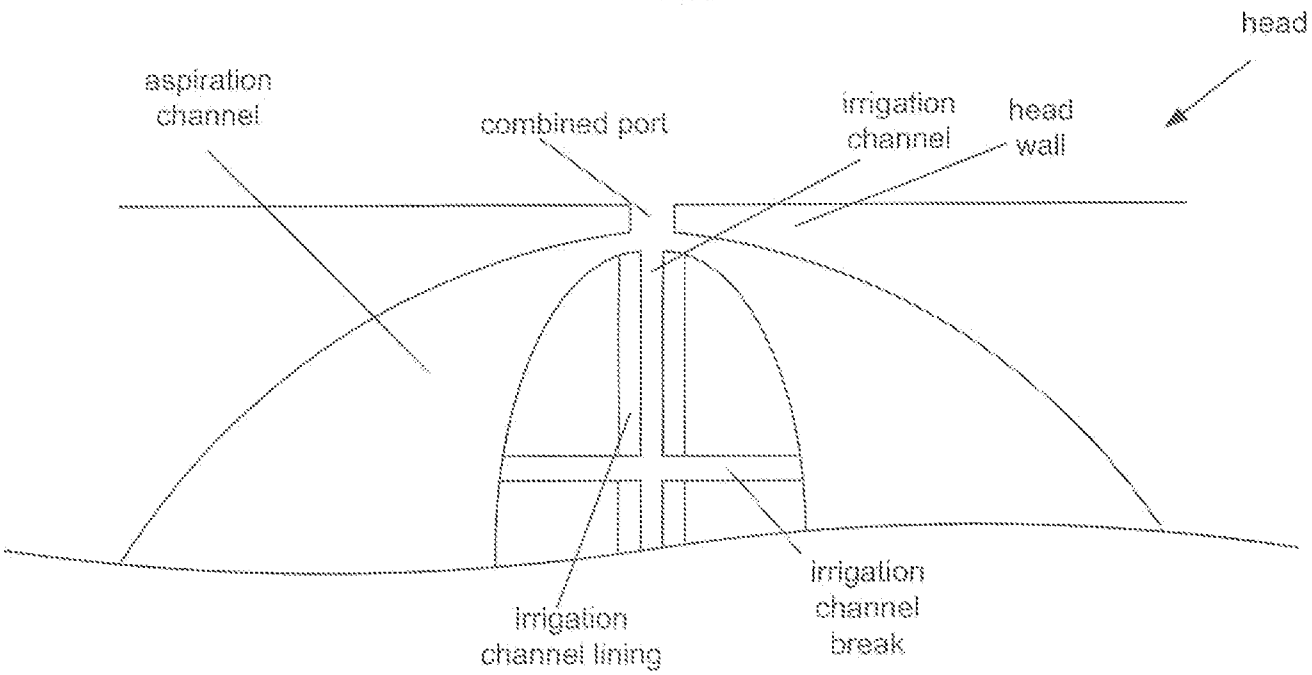
head
aspiration channel
combined port
irrigation channel
head wall
irrigation channel break
irrigation channel lining

Fig. 19

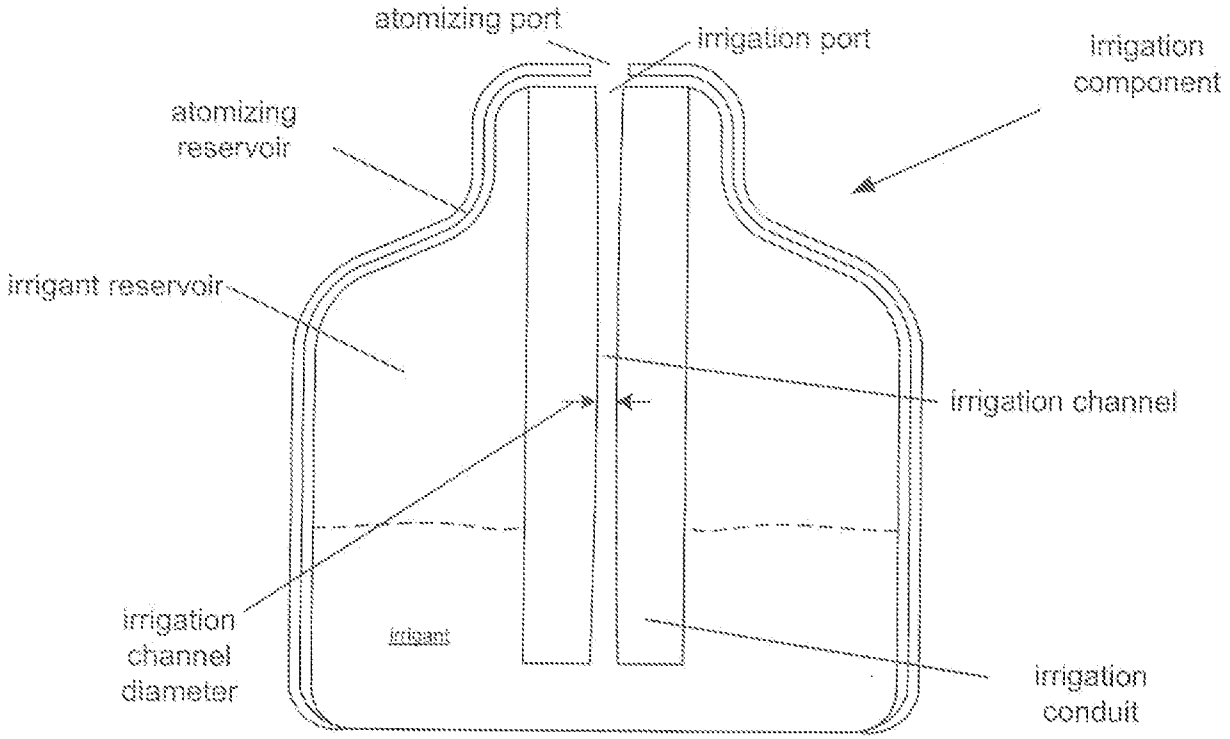
atomizing port
irrigation port
irrigation component
atomizing reservoir
irrigant reservoir
irrigation channel
irrigation channel diameter
irrigant
irrigation conduit

Fig. 20

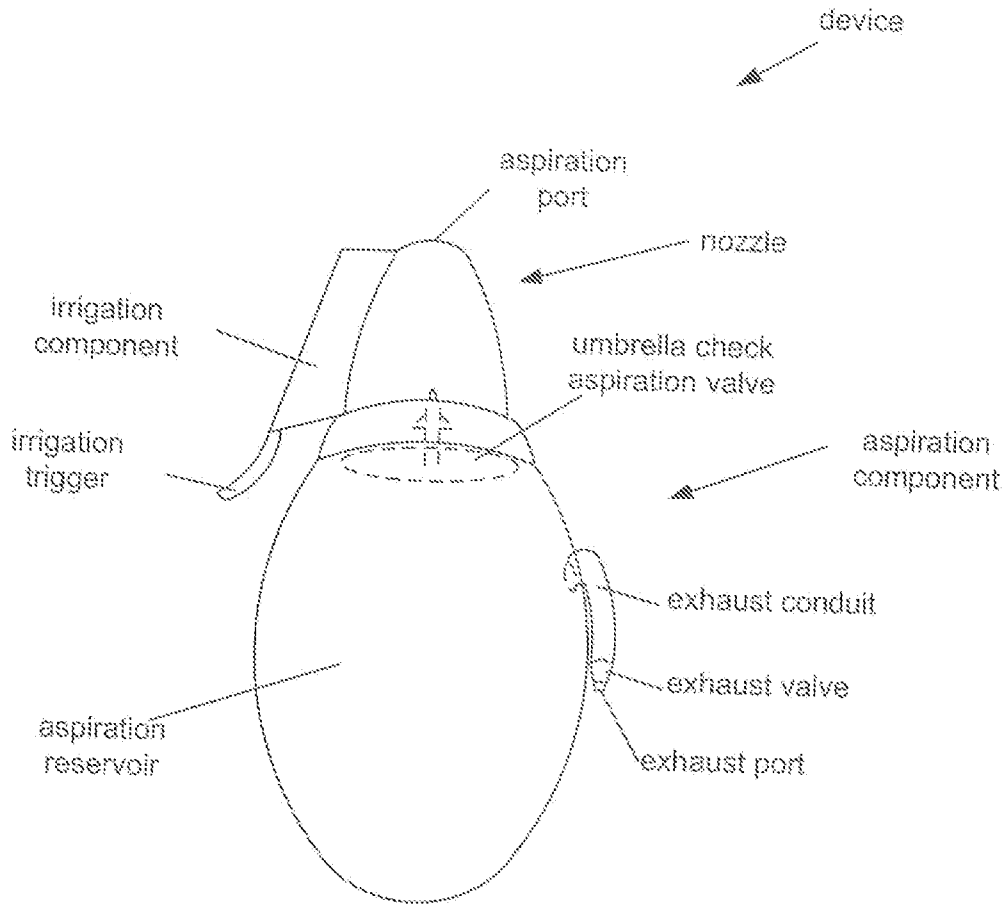
device
aspiration port
nozzle
irrigation component
umbrella check aspiration valve
irrigation trigger
aspiration component
exhaust conduit
exhaust valve
aspiration reservoir
exhaust port

Fig. 21

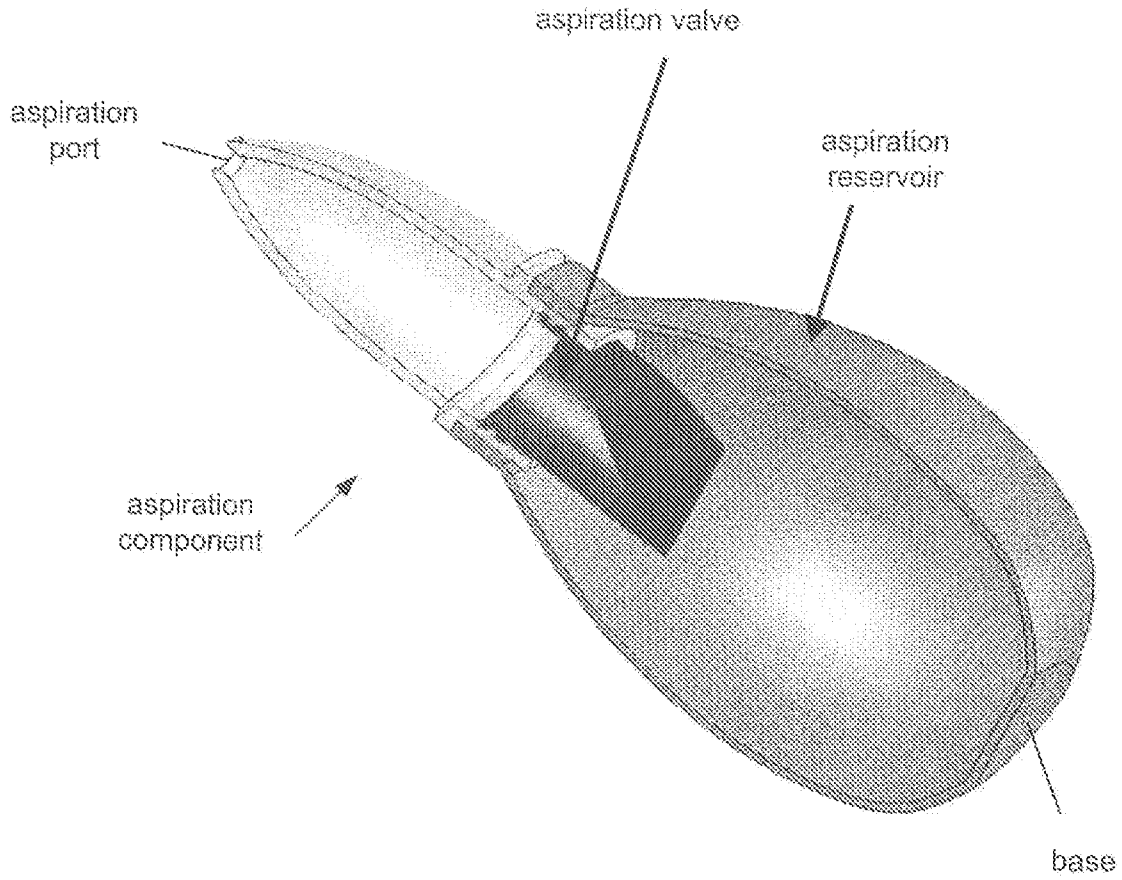
aspiration valve
aspiration port
aspiration reservoir
aspiration component
base

Fig. 22

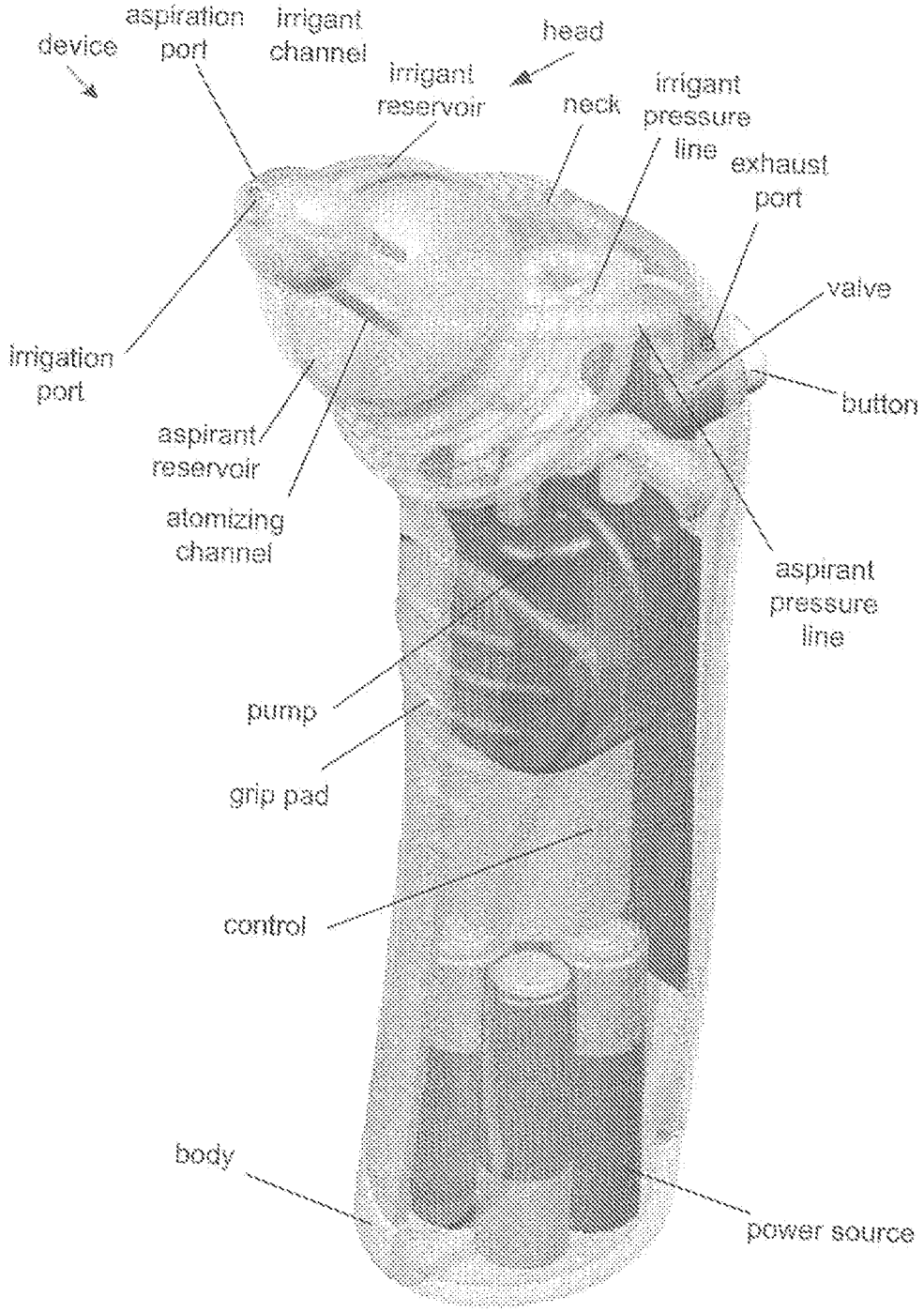
device
aspiration port
irrigant channel
head
irrigant reservoir
neck
irrigant pressure line
exhaust port
valve
button
irrigation port
aspirant reservoir
atomizing channel
aspirant pressure line
pump
grip pad
control
body
power source

Fig. 23

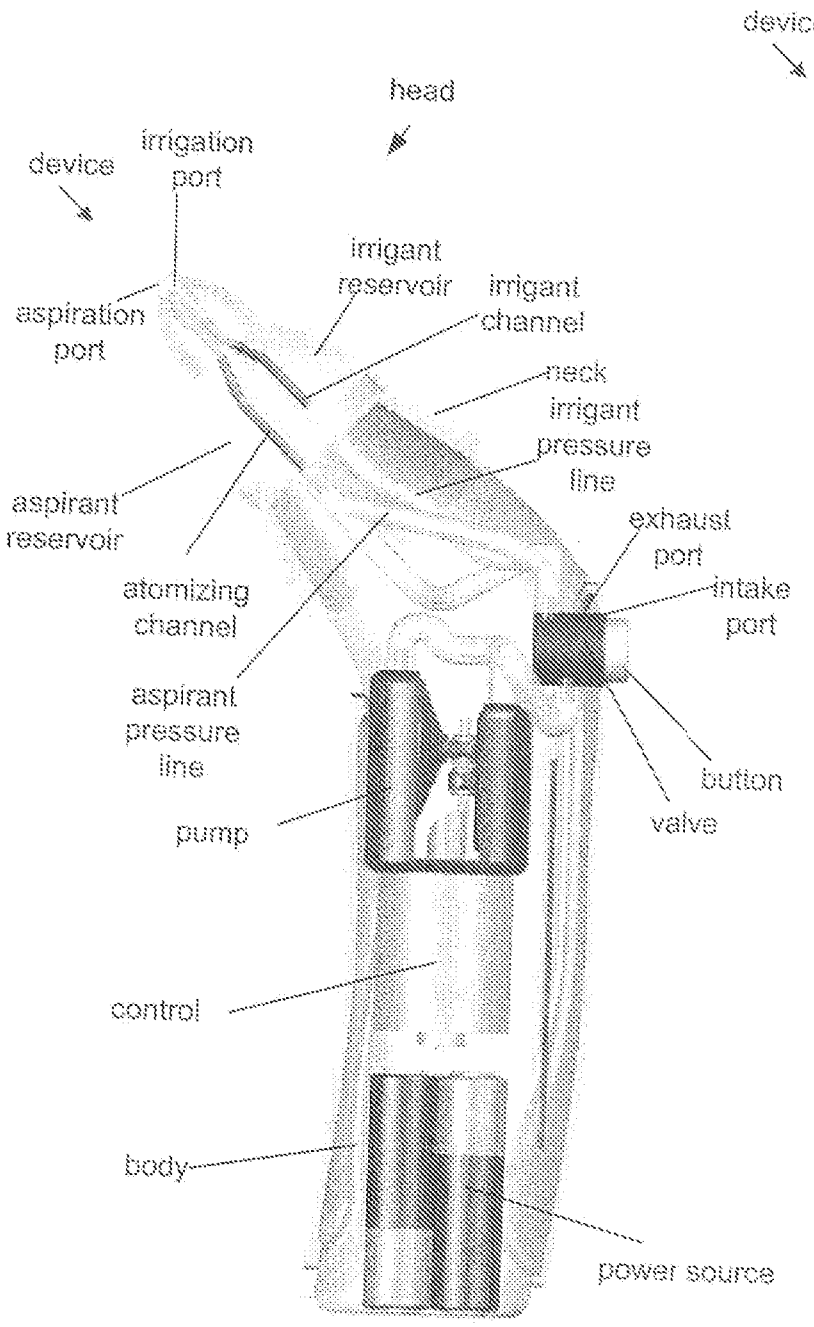
device
head
device
irrigation port
aspiration port
irrigant reservoir
irrigant channel
neck
irrigant pressure line
aspirant reservoir
exhaust port
atomizing channel
intake port
aspirant pressure line
button
valve
pump
control
body
power source

Fig. 24

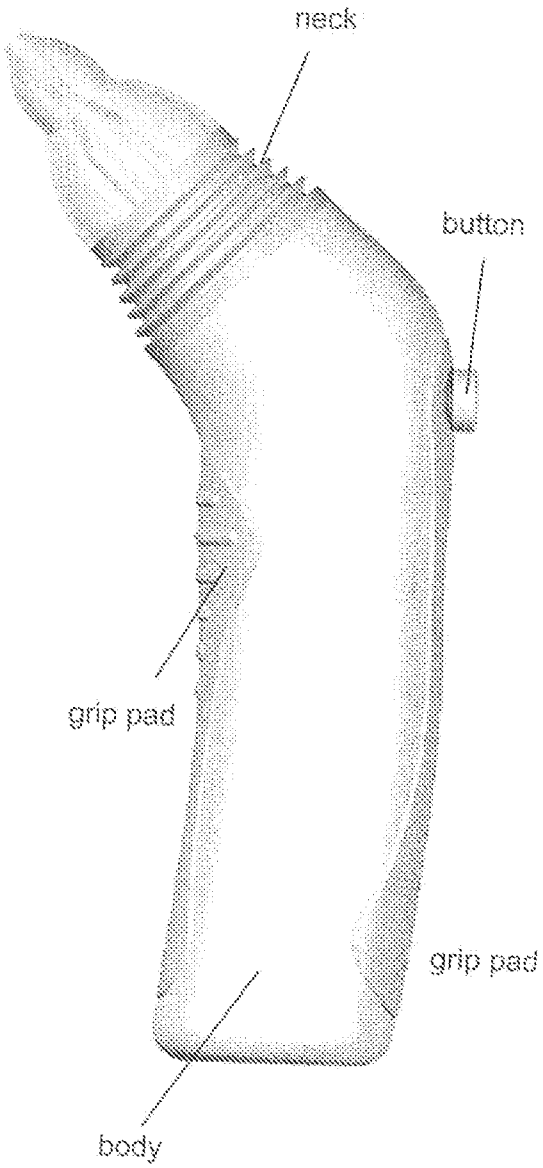
neck
button
grip pad
grip pad
body

Fig. 25

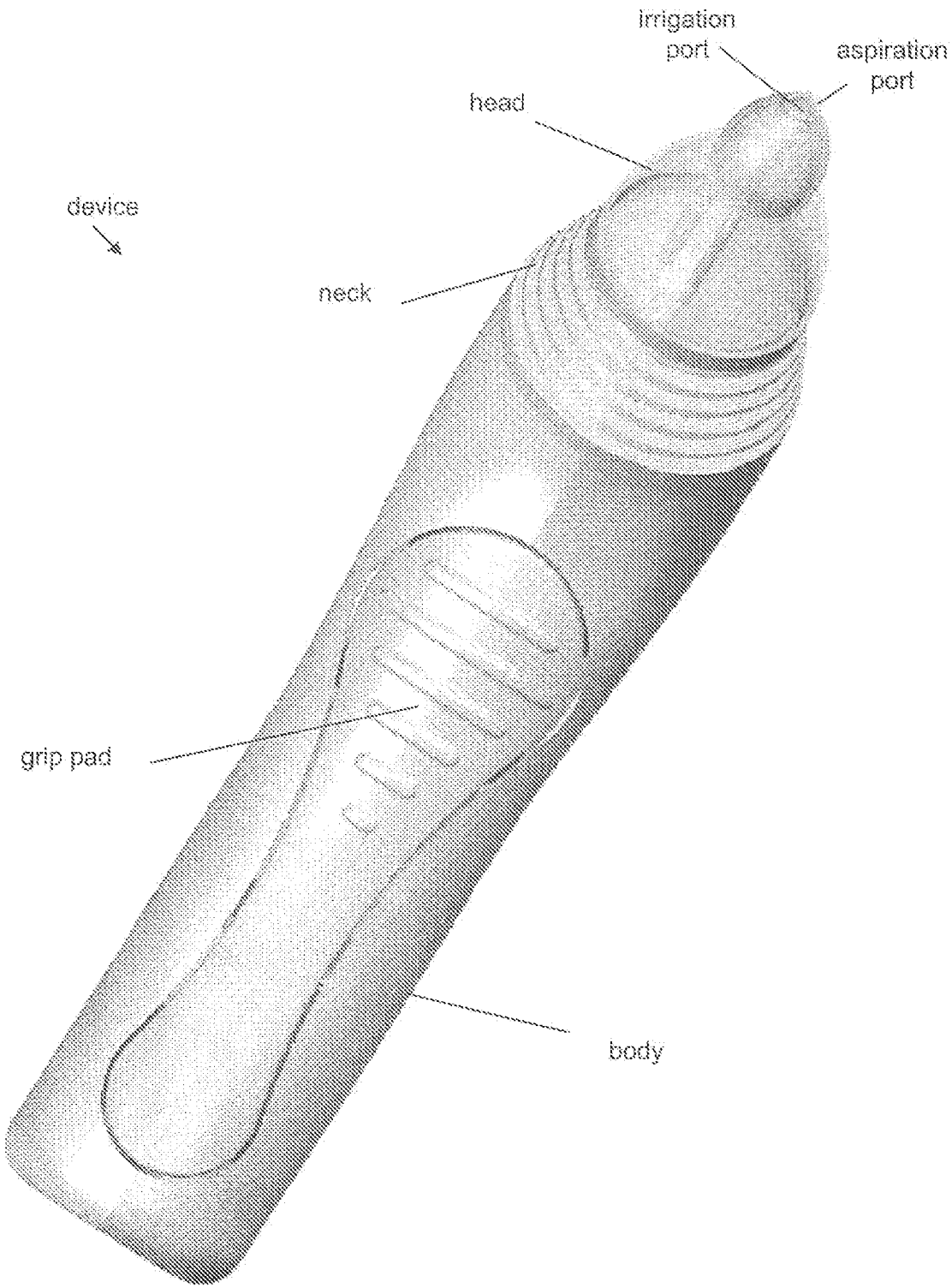
irrigation port
aspiration port
head
device
neck
grip pad
body

Fig. 26

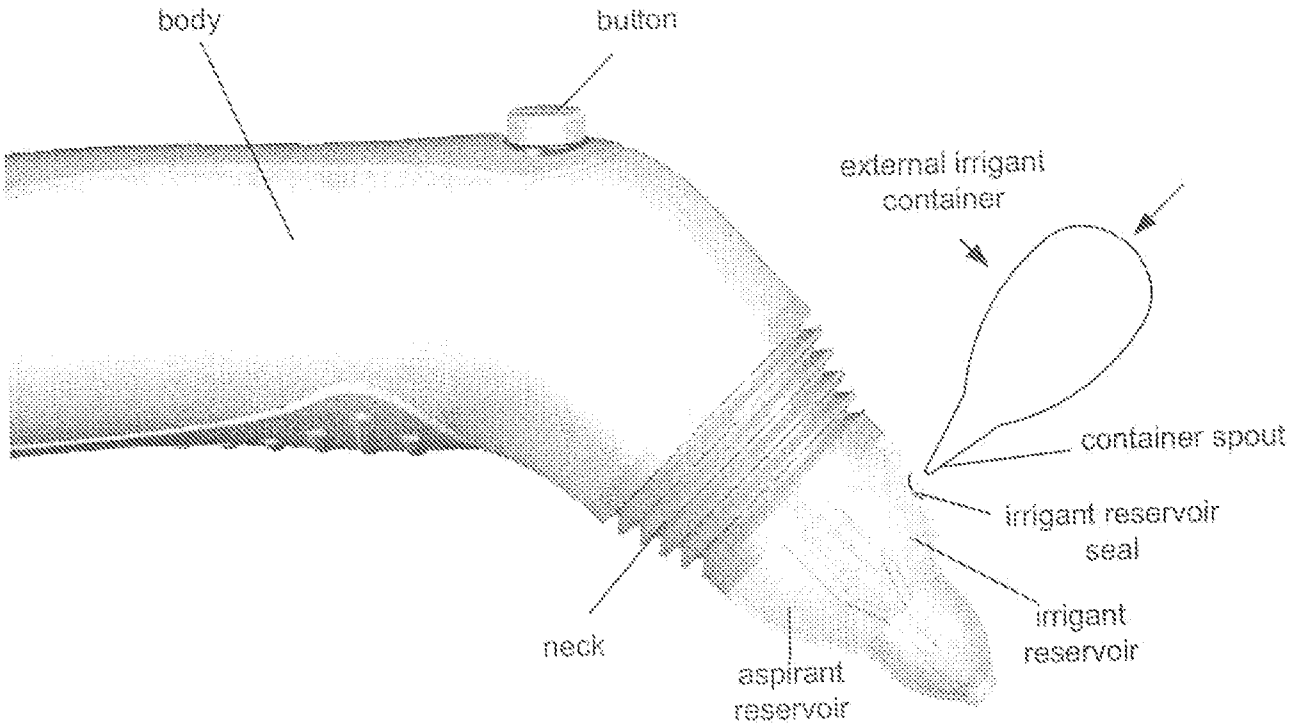
body
button
external irrigant container
container spout
irrigant reservoir seal
irrigant reservoir
neck
aspirant reservoir

Fig. 27

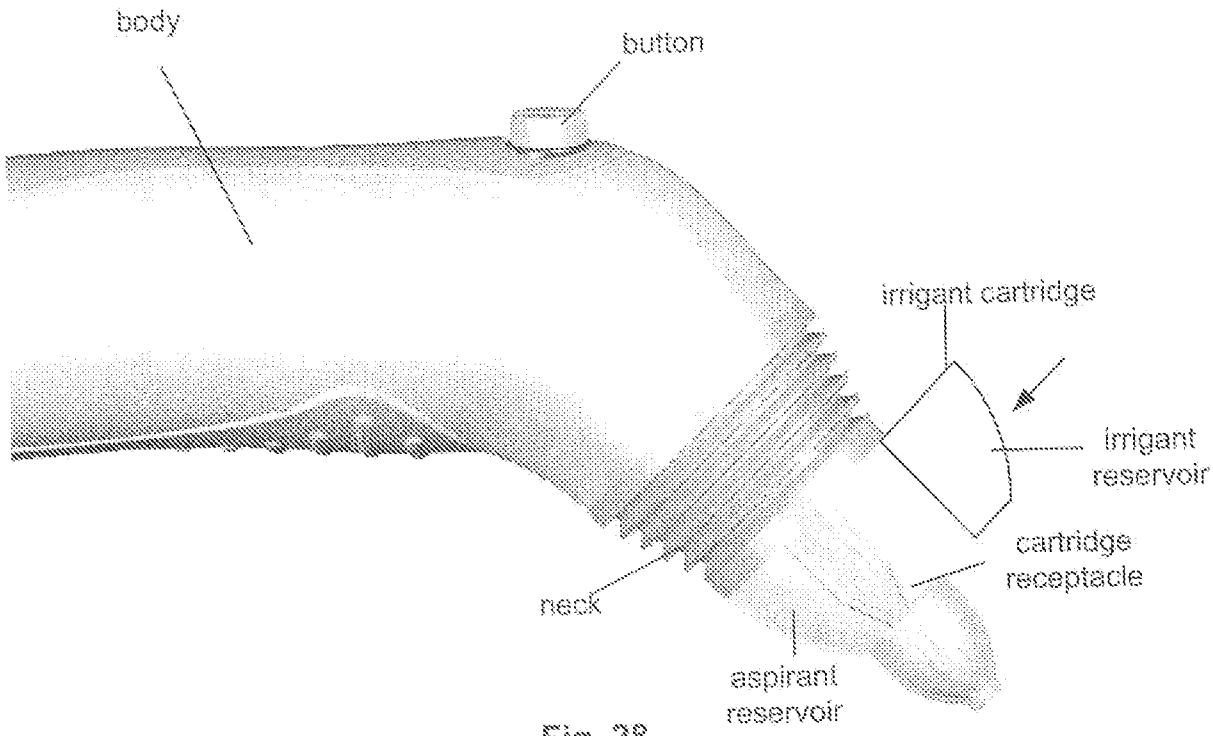
body
button
irrigant cartridge
irrigant reservoir
cartridge receptacle
neck
aspirant reservoir

Fig. 28

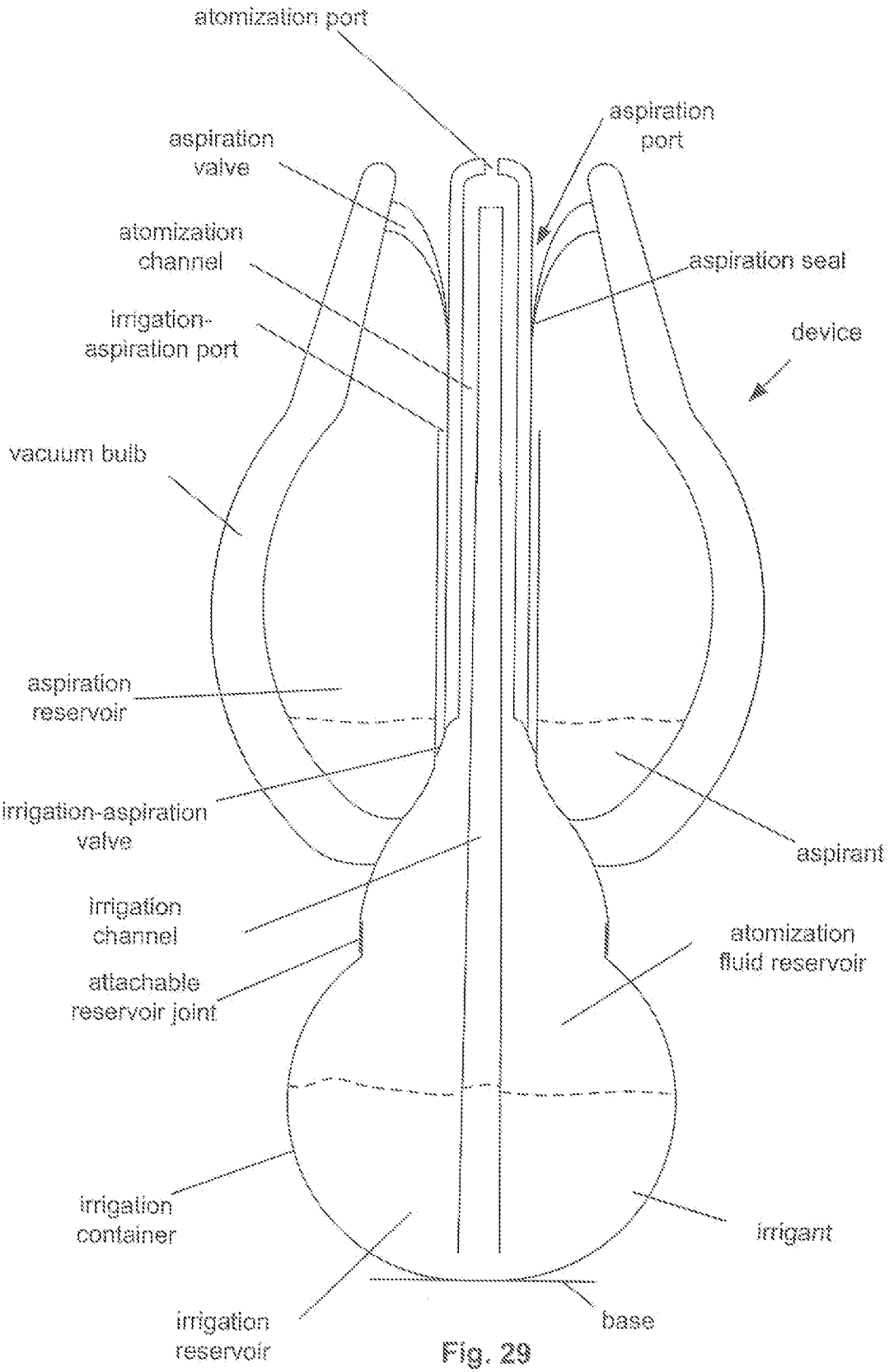
atomization port
aspiration port
aspiration valve
atomization channel
aspiration seal
irrigation-aspiration port
device
vacuum bulb
aspiration reservoir
irrigation-aspiration valve
aspirant
irrigation channel
atomization fluid reservoir
attachable reservoir joint
irrigation container
irrigant
irrigation reservoir
base

Fig. 29

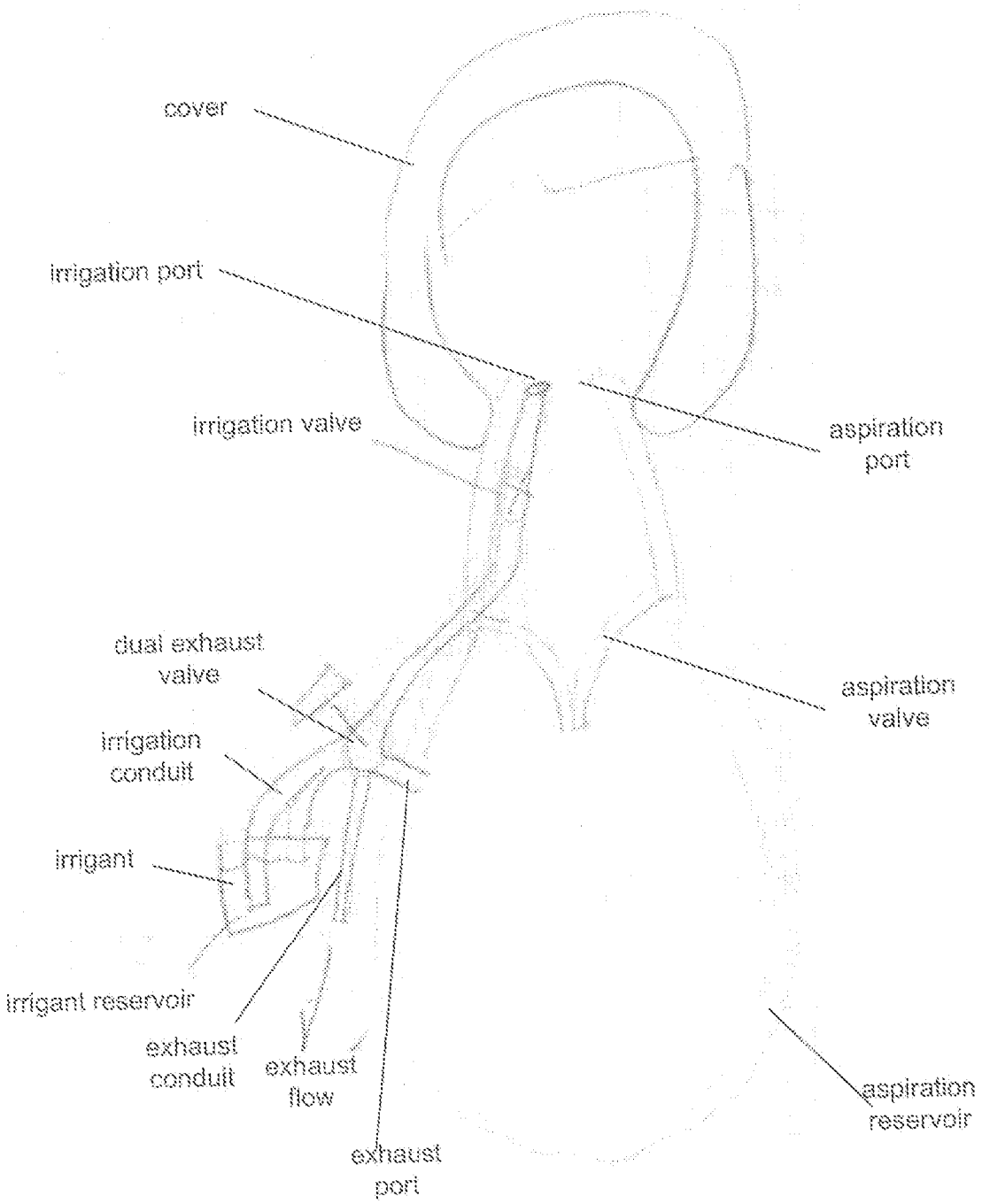
cover
irrigation port
irrigation valve
aspiration port
dual exhaust valve
aspiration valve
irrigation conduit
irrigant
irrigant reservoir
exhaust conduit
exhaust flow
aspiration reservoir
exhaust port

Fig. 30

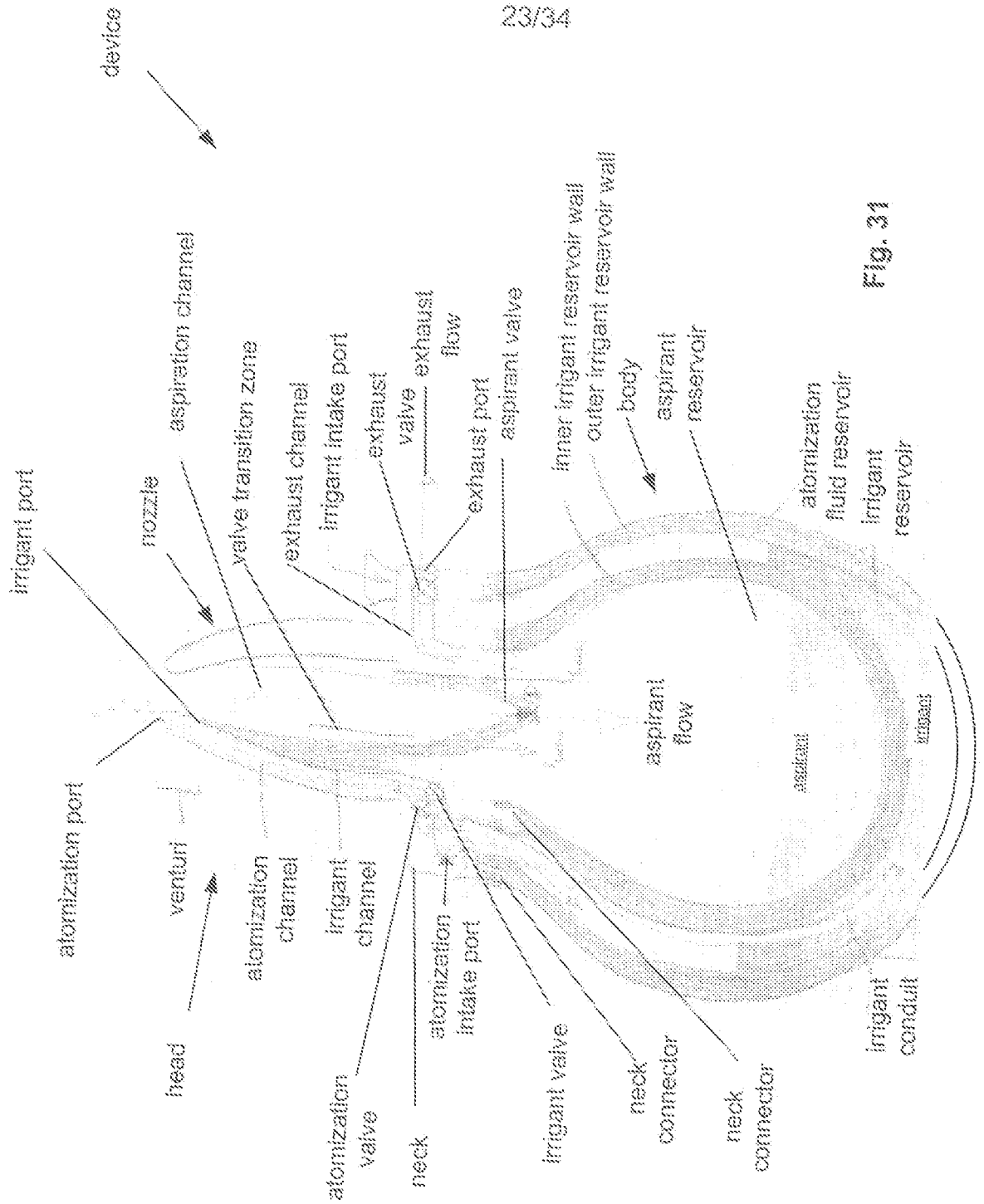
device
irrigant port
nozzle
aspiration channel
valve transition zone
exhaust channel
irrigant intake port
exhaust valve
exhaust flow
exhaust port
aspirant valve
inner irrigant reservoir wall
outer irrigant reservoir wall
body
aspirant reservoir
atomization fluid reservoir
irrigant reservoir
atomization port
venturi
atomization channel
irrigant channel
atomization valve
neck
atomization intake port
irrigant valve
neck connector
neck connector
aspirant flow
aspirant
irrigant
irrigant conduit

Fig. 31

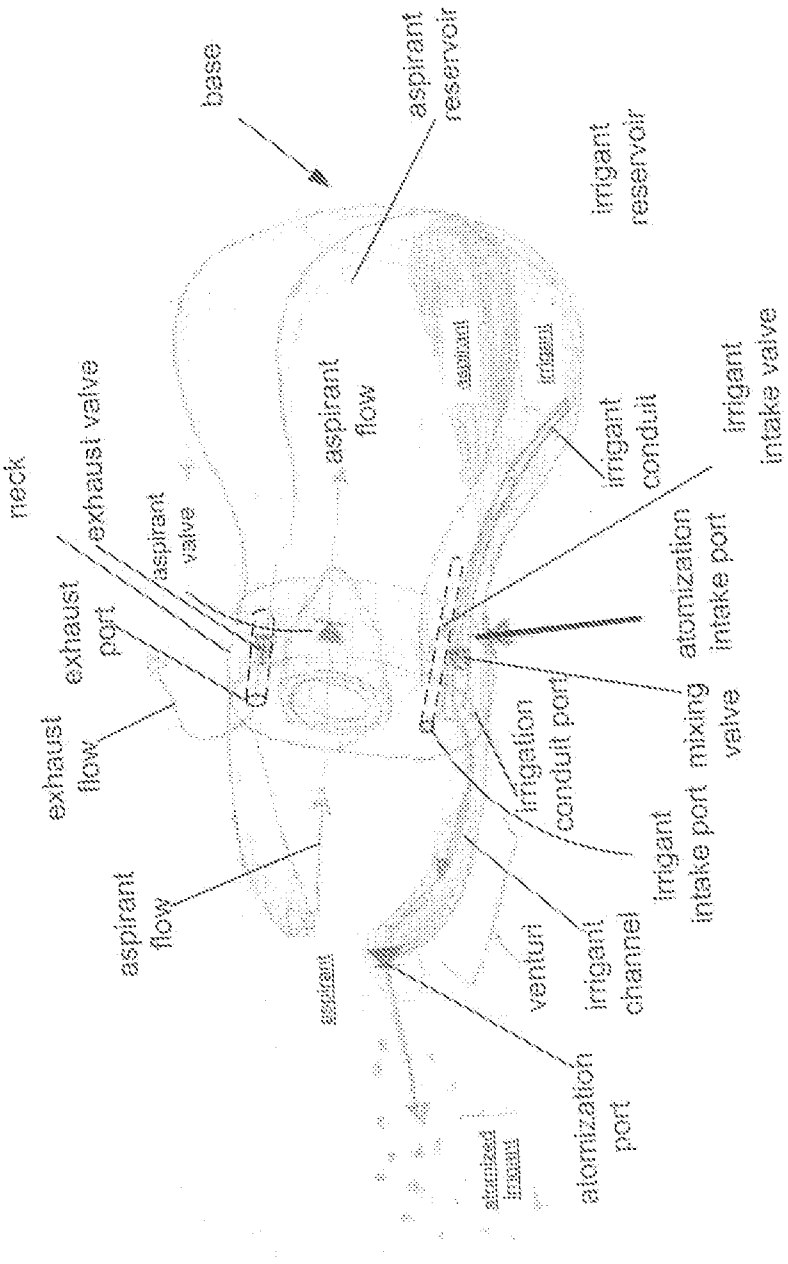
base
aspirant reservoir
irrigant reservoir
neck
exhaust valve
aspirant valve
aspirant flow
irrigant conduit
irrigant intake valve
exhaust port
exhaust flow
atomization intake port
irrigation conduit port
mixing valve
aspirant flow
irrigant intake port
venturi
irrigant channel
atomization port
atomized irrigant

Fig. 32

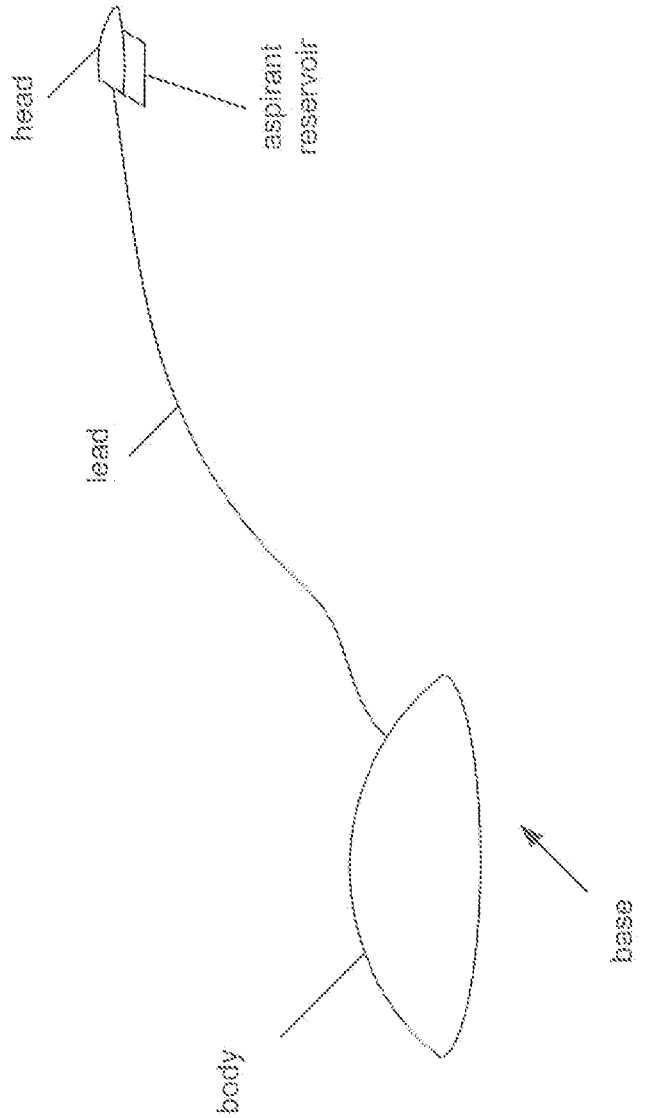

Fig. 33

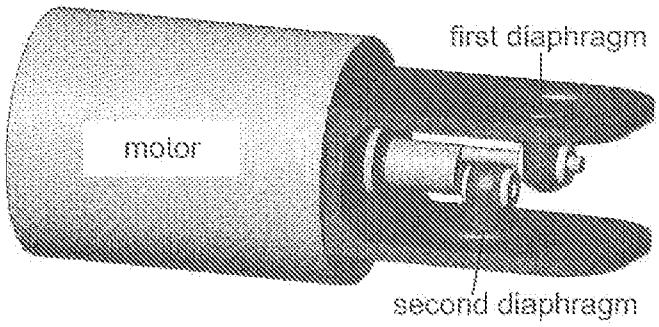

Fig. 34a

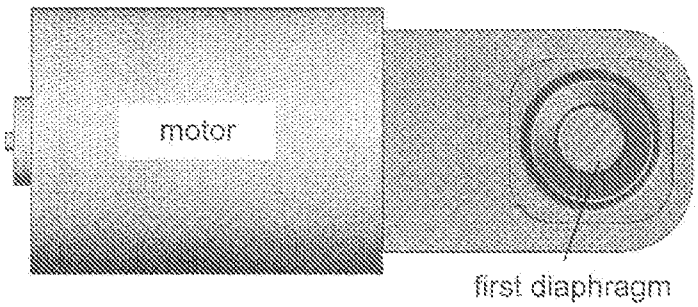

Fig. 34b

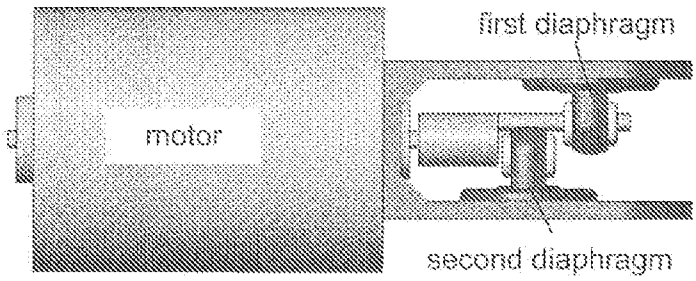

Fig. 34c

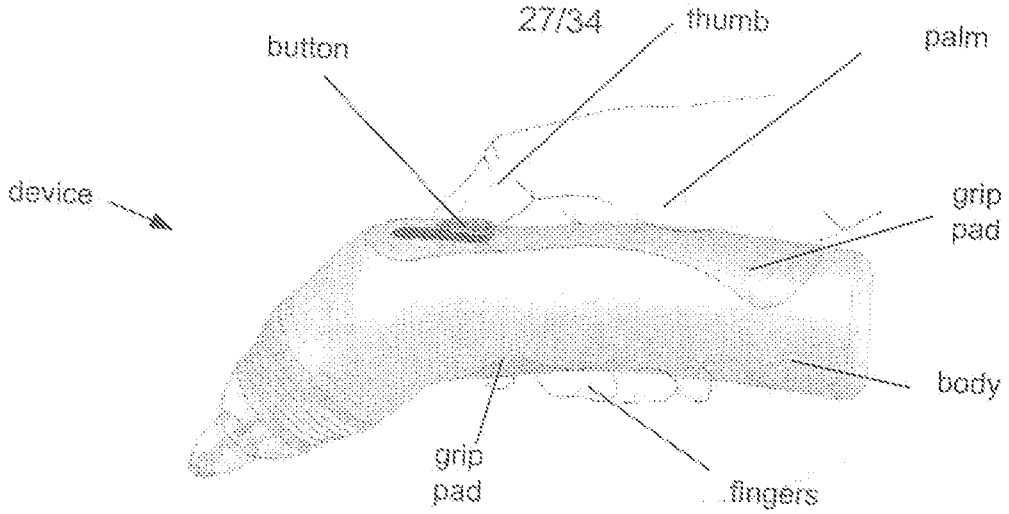

Fig. 35

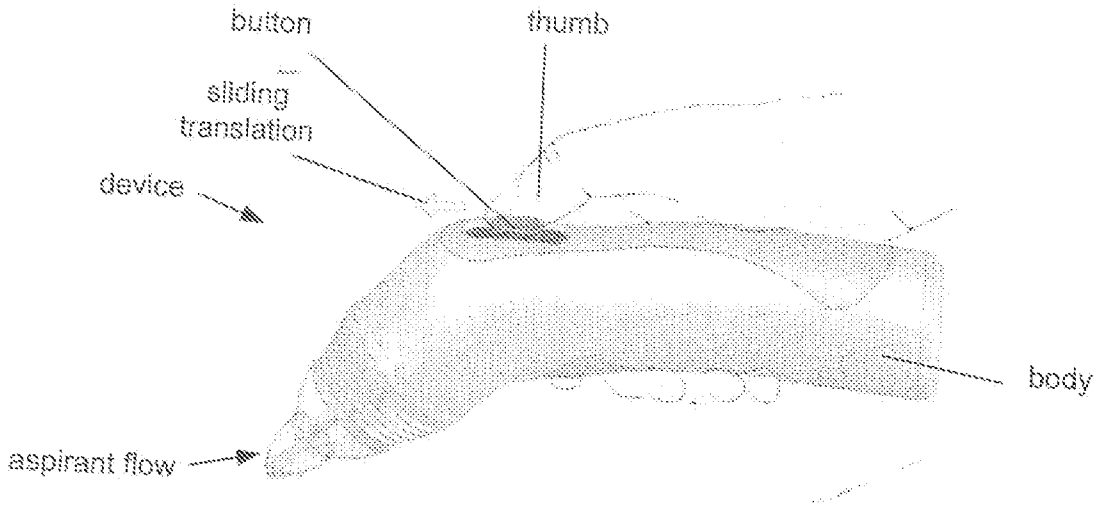

Fig. 36

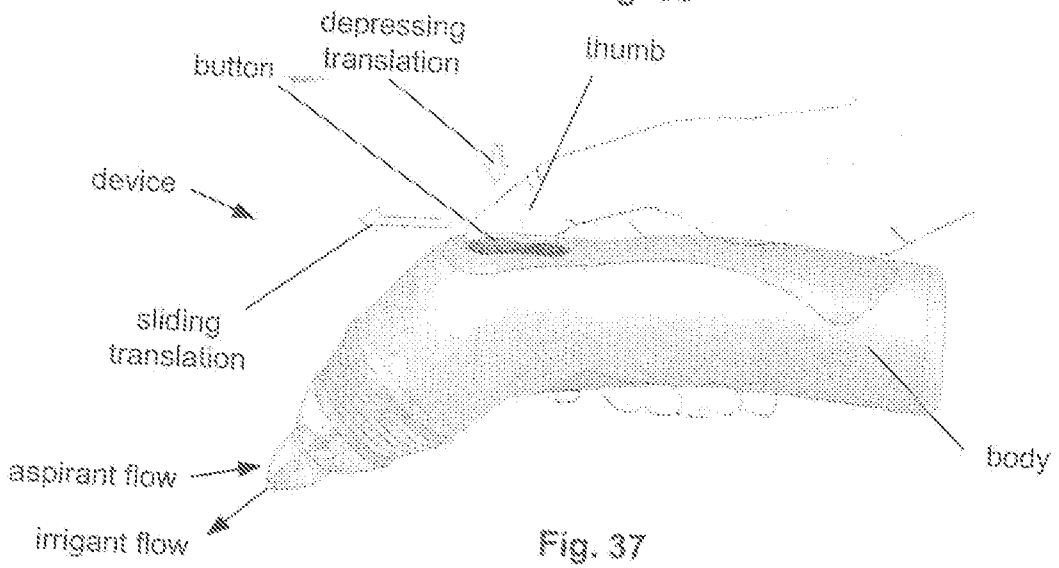

Fig. 37

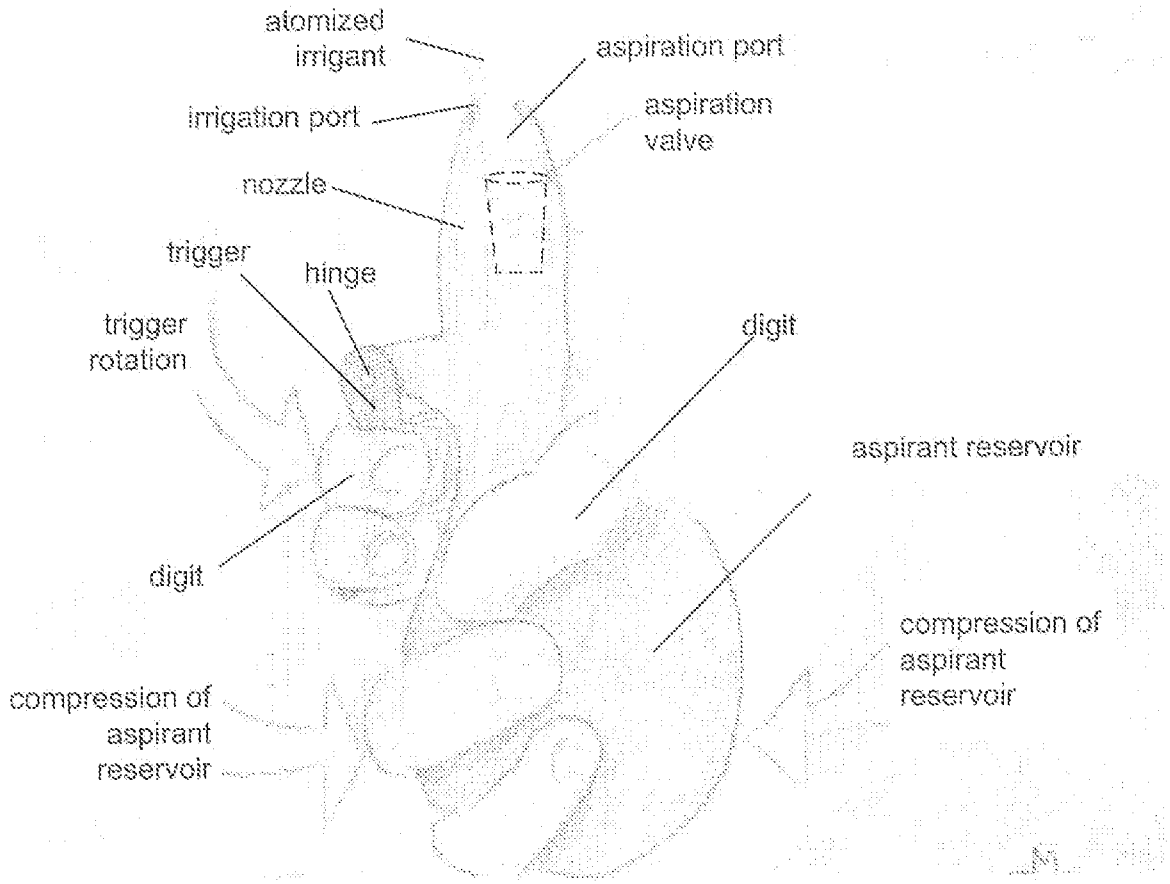
atomized irrigant
aspiration port
irrigation port
aspiration valve
nozzle
trigger
hinge
trigger rotation
digit
aspirant reservoir
digit
compression of aspirant reservoir
compression of aspirant reservoir

Fig. 38

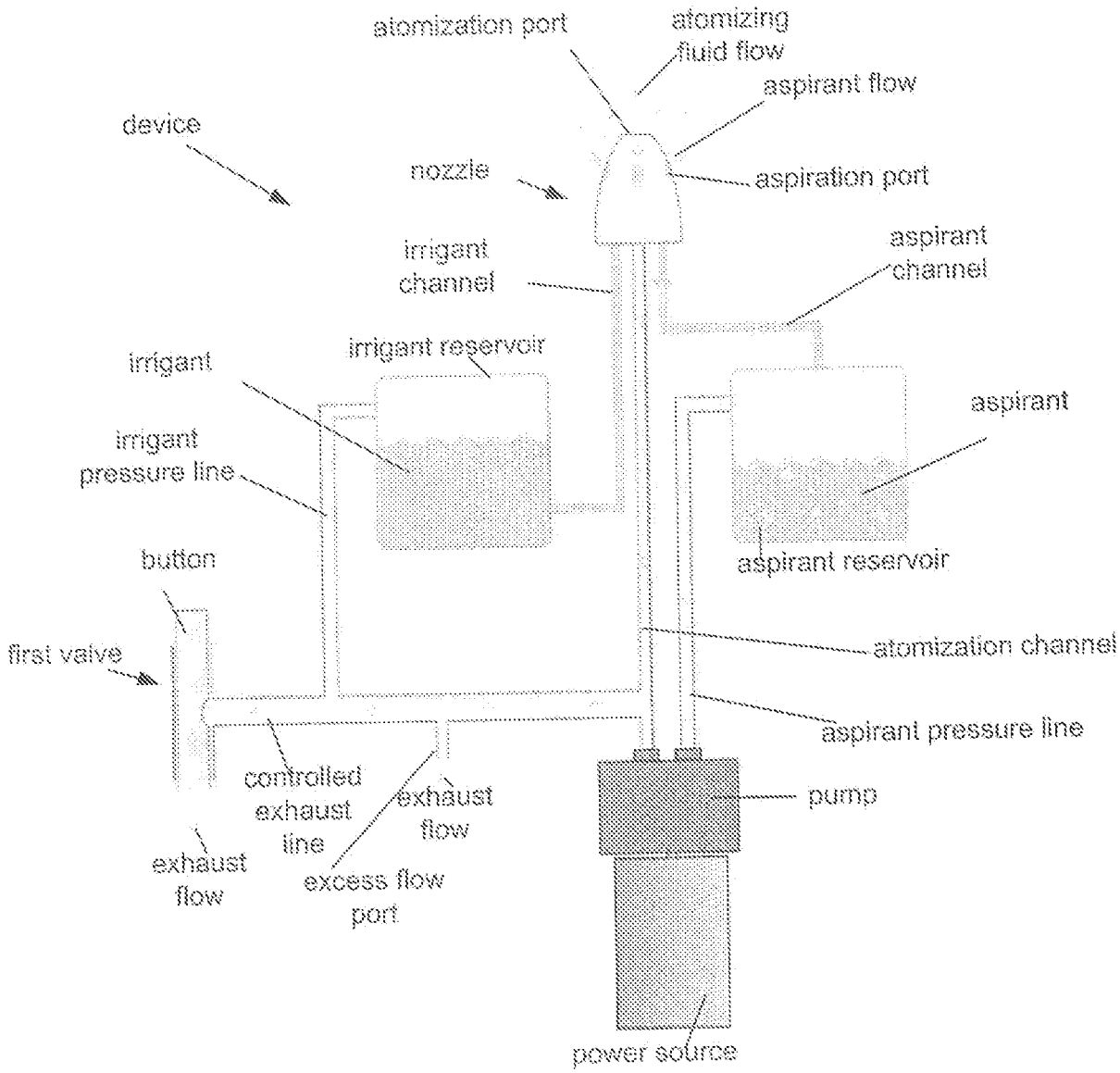
atomization port
atomizing fluid flow
aspirant flow
device
nozzle
aspiration port
irrigant channel
aspirant channel
irrigant reservoir
irrigant
aspirant
irrigant pressure line
button
aspirant reservoir
first valve
atomization channel
aspirant pressure line
controlled exhaust line
exhaust flow
pump
exhaust flow
excess flow port
power source

Fig. 39

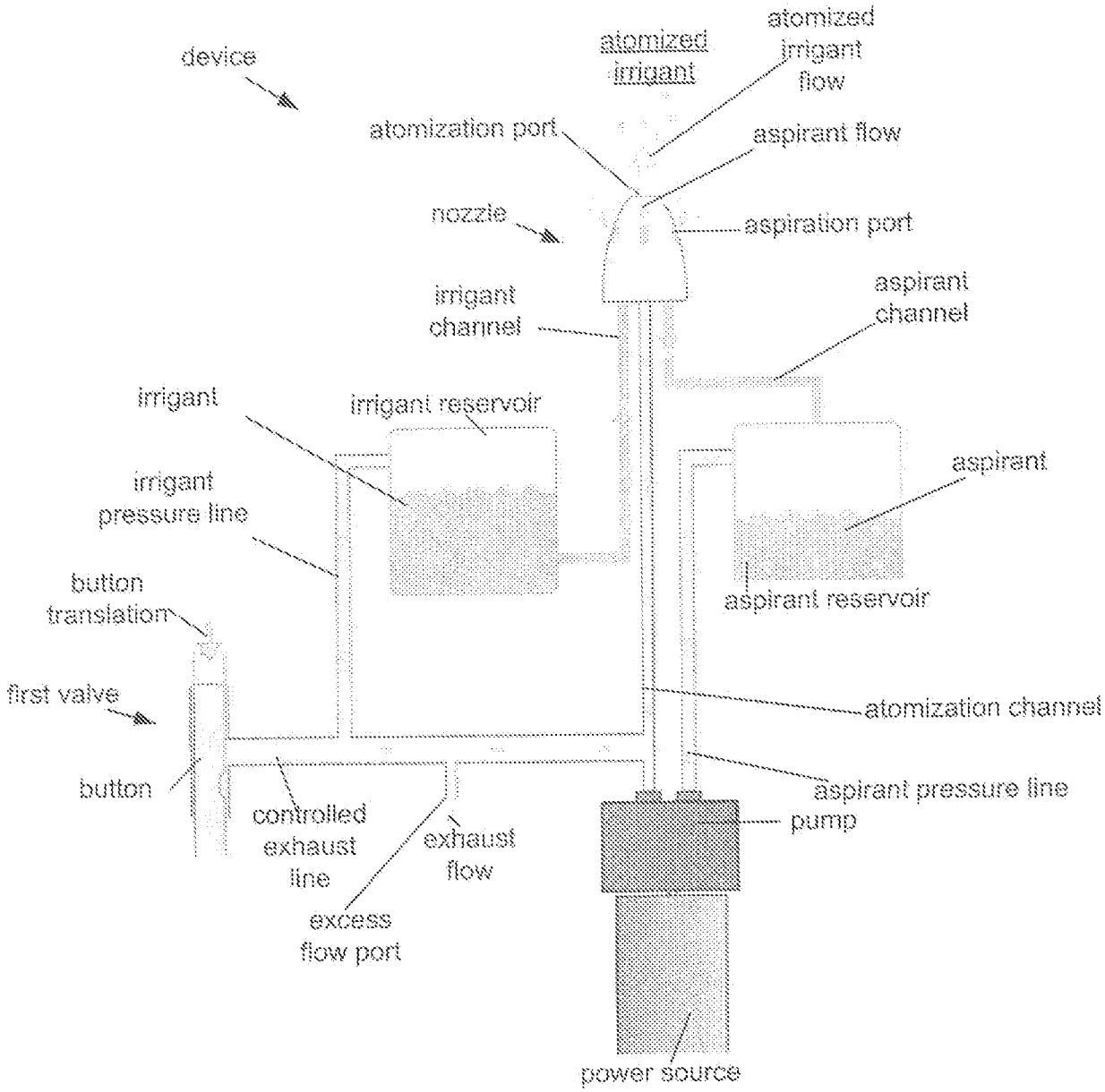
device
atomized irrigant
atomized irrigant flow
atomization port
aspirant flow
nozzle
aspiration port
irrigant channel
aspirant channel
irrigant
irrigant reservoir
irrigant pressure line
aspirant
aspirant reservoir
button translation
first valve
atomization channel
button
aspirant pressure line
pump
controlled exhaust line
exhaust flow
excess flow port
power source

Fig. 40

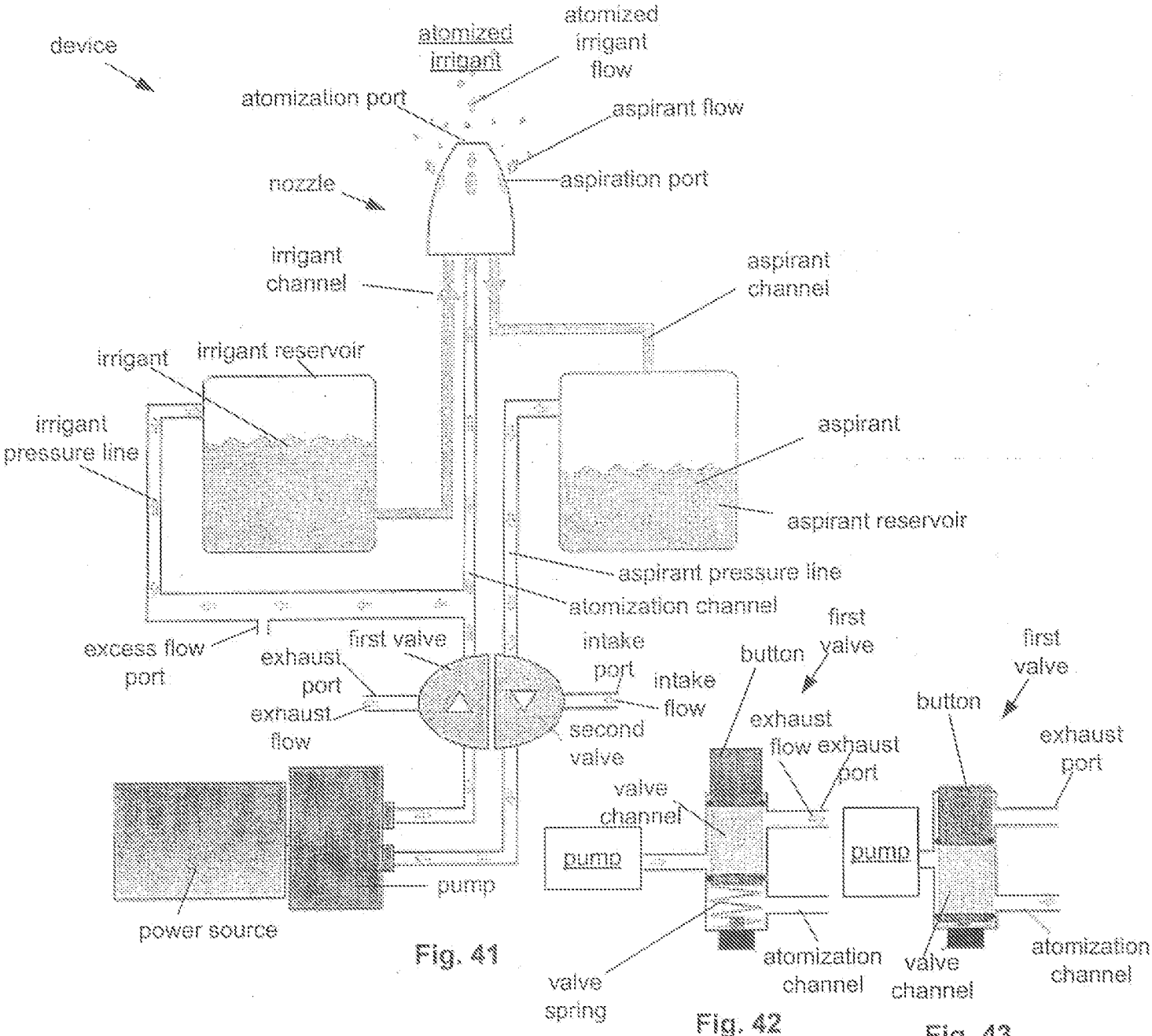

Fig. 41

Fig. 42

Fig. 43

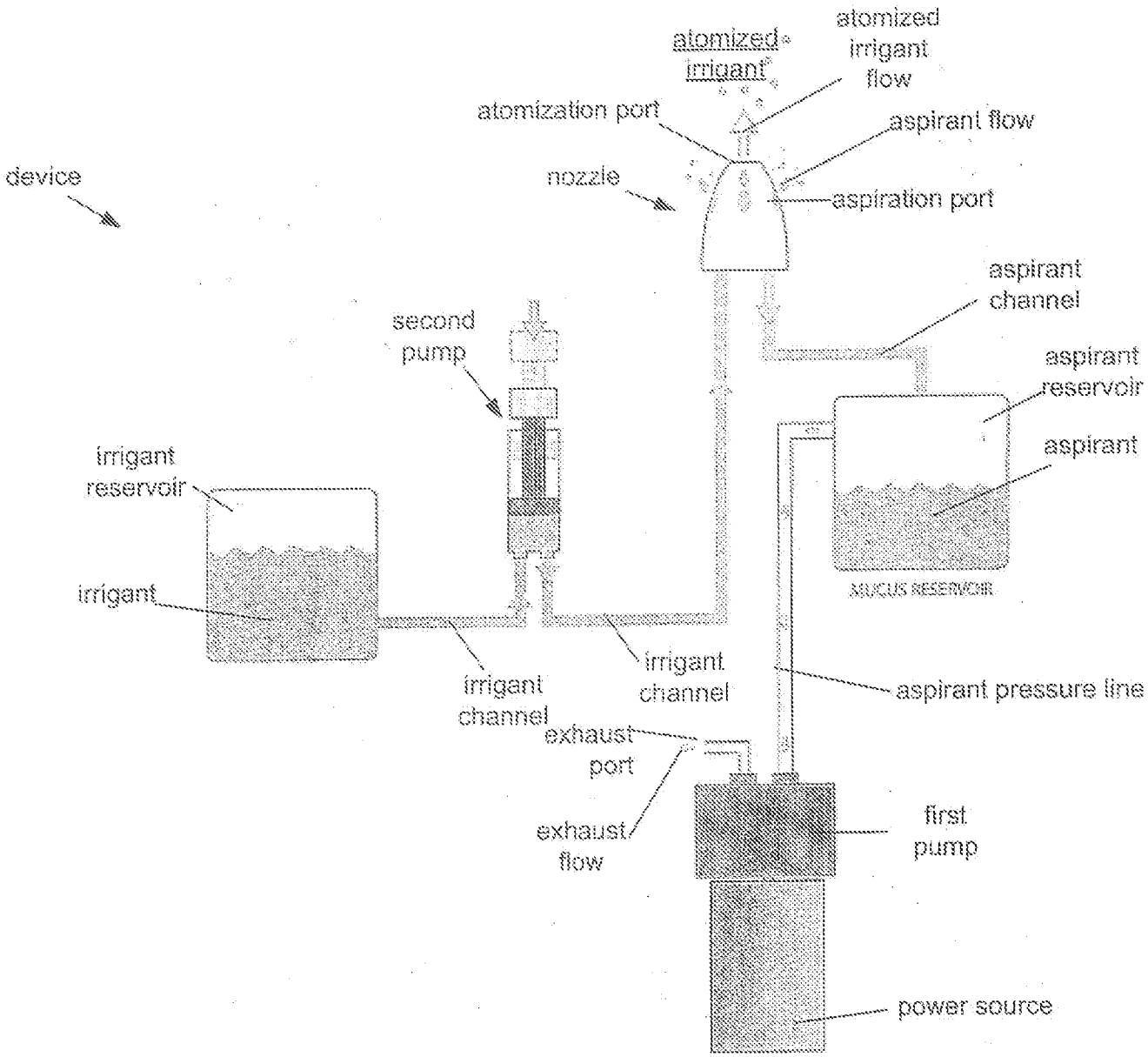
atomized irrigant
atomized irrigant flow
atomization port
aspirant flow
device
nozzle
aspiration port
aspirant channel
second pump
aspirant reservoir
aspirant
irrigant reservoir
irrigant
MUCUS RESERVOIR
irrigant channel
irrigant channel
aspirant pressure line
exhaust port
exhaust flow
first pump
power source

Fig. 44

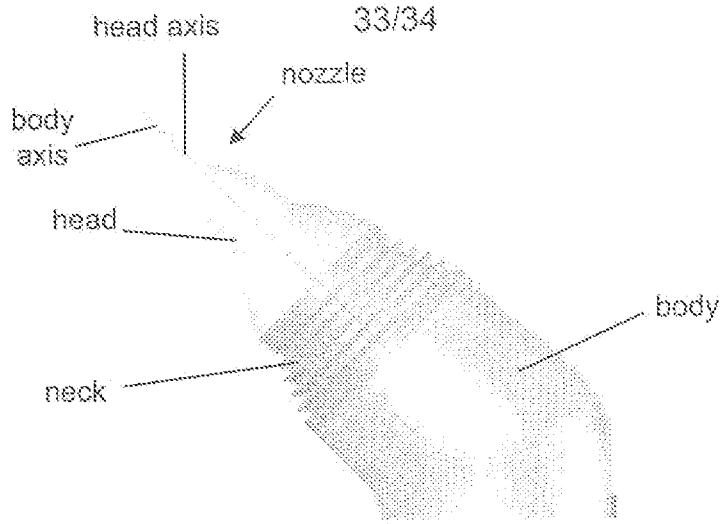

Fig. 45

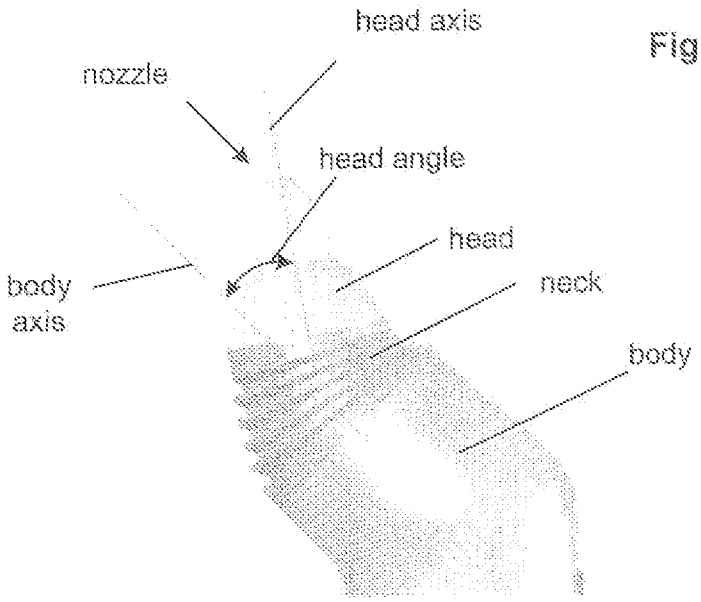

Fig. 46

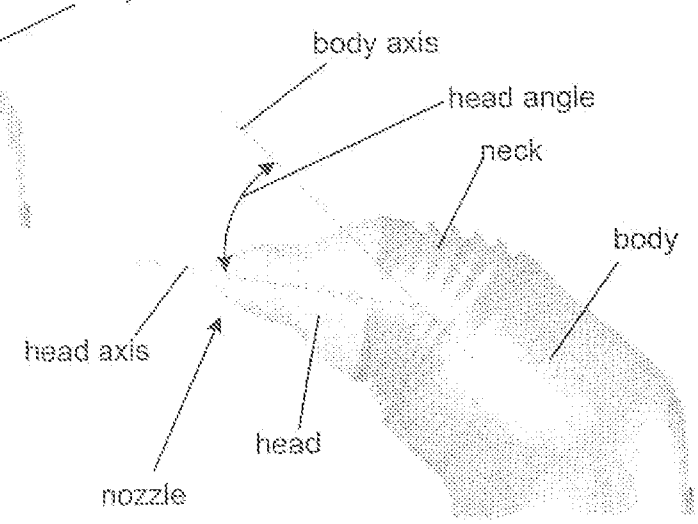

Fig. 47

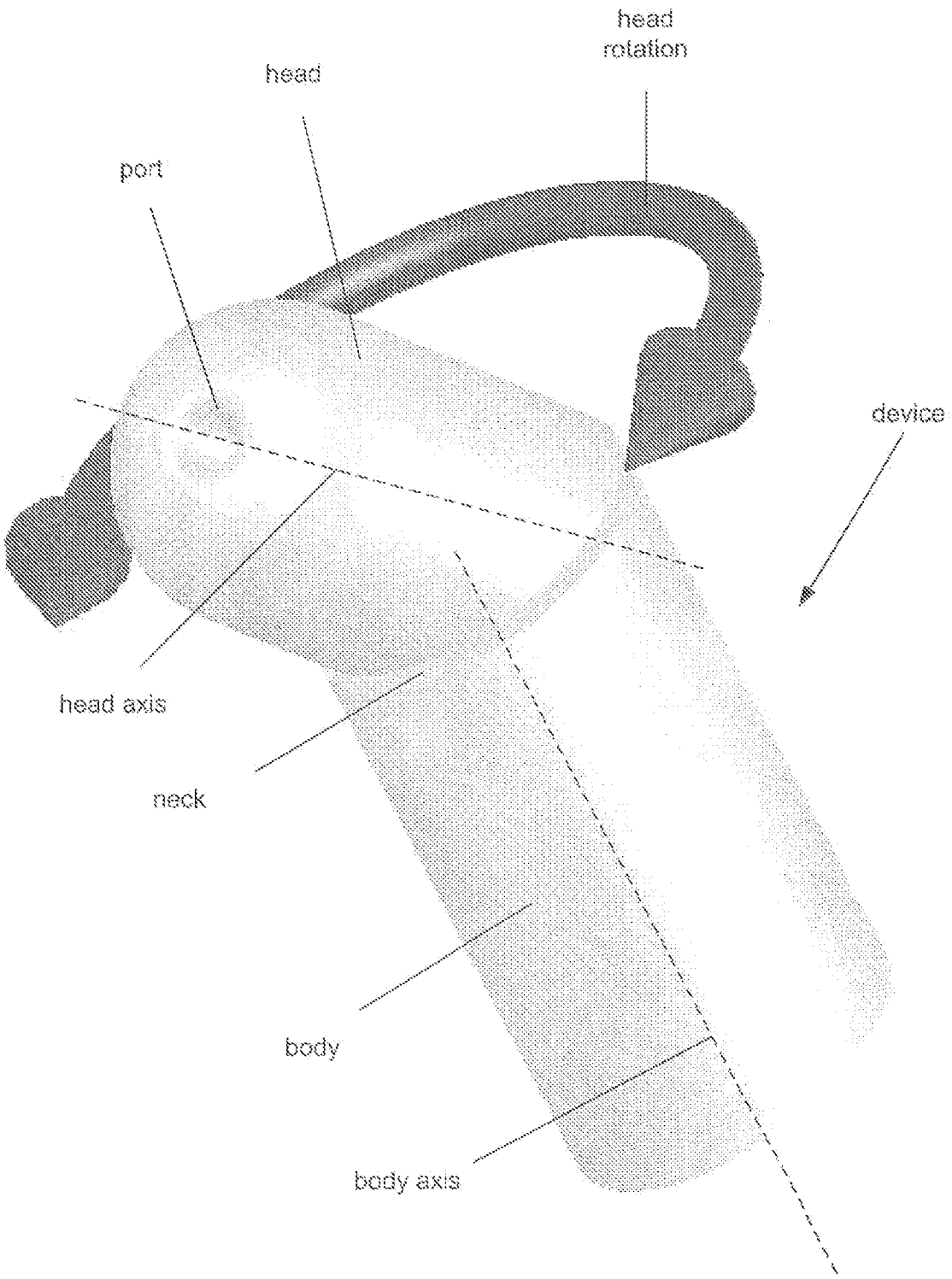
head
rotation
head
port
device
head axis
neck
body
body axis

Fig. 48