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The following enclosures are transmitted herewith to be filed in the Provisional Patent Application of:

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APPLICATION ELEMENTS:

- (X) Specification in 40 pages.
- (X) Drawings in 25 sheets.
- (X) Return prepaid postcard.

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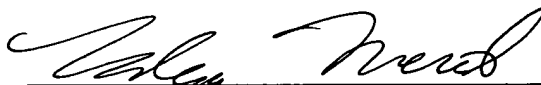
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APPARATUS AND METHODS FOR TREATING THE SKINBackground of the InventionField of the Invention

[0001] The invention relates in general to the field of skin treatment, and more specifically to apparatuses and methods for treating a person's skin.

Description of the Related Art

[0002] Abrasion of the outer layer or epidermis of the skin is desirable to smooth or blend scars, blemishes, or other skin conditions that may be caused by, for example, acne, sun exposure, and aging. Standard techniques used to abrade the skin have generally been separated into two fields referred to as dermabrasion and microdermabrasion. Both techniques remove portions of the epidermis called the stratum corneum, which the body interprets as a mild injury. The body then replaces the lost skin cells, resulting in a new outer layer of skin. Additionally, despite the mild edema and erythema associated with the procedures, the skin looks and feels smoother because of the new outer layer of skin.

[0003] Dermabrasion refers to a procedure in which the surface of the skin is removed due to mechanical rubbing by a handpiece with an abrasive element that is often in the form of a burr, wheel, or disc. This process tends to be painful and messy. In fact, the procedure is sometimes painful enough to require a local anesthetic. Dermabrasion leaves the skin red and raw-looking. The removed skin can take several months to regrow and heal. Recent efforts have led to the use of lasers instead of abrasive elements, which have resulted in less bleeding, but the pain and mess remains.

[0004] Efforts have been made to decrease the mess caused by the process waste, such as removed skin and blood, by adding a suction element. As the process waste is drawn into the suction opening, skin that has not been removed is also pulled against the grit surrounding the suction opening, so the procedure remains fairly messy due to the abrasion that takes place outside of the handpiece by the grit.

[0005] Microdermabrasion refers generally to a procedure in which the surface of the skin is removed due to mechanical rubbing by a handpiece emitting a stream of sand or grit. For example, a handpiece can be used to direct an air flow containing tiny crystals of

aluminum oxide, sodium chloride, or sodium bicarbonate. The momentum of the grit tends to wear away two to three cell layers of the skin with each pass of the handpiece. Alternatively, new “crystal-free” microdermabrasion techniques utilize a diamond-tipped handpiece without a stream of grit.

[0006] Efforts to add a suction element have been more successful in microdermabrasion than in dermabrasion because the handpiece applying the stream of grit is more controllable to a localized area. That is, as the removed skin is drawn into the suction opening, skin that has not been removed is also pulled towards the handpiece where it is treated with the grit stream, allowing for simultaneous local treatment and suction.

[0007] Microdermabrasion removes moisture from the skin, so the procedure is always followed by the application of moisturizing creams. However, similar to topical application of moisturizing creams prior to microdermabrasion, the moisturizing elements only work as deep as the active ingredients can passively migrate through the remaining epidermis.

Summary of the Invention

[0008] In some embodiments, an apparatus for treating skin has a console with a user input device and a handpiece assembly. The handpiece assembly is configured to treat skin. A fluid line provides fluid communication between the console and the handpiece assembly. A manifold system is coupled to the console and controlled by the user input device, such as a computer, touchscreen, keyboard, and the like. The manifold system is configured to hold releasably a plurality of fluid sources and deliver fluid from at least one of the plurality of fluid sources to the handpiece assembly.

[0009] In some embodiments, a tip comprising a skirt portion is configured to couple to a handpiece for treating a target area on a patient's skin. A central body portion is coupled to the skirt portion. A first passage extends through the central body portion and is configured to receive a fluid from the handpiece. At least one second passageway extending through the central body portion and is configured to convey the fluid back into the handpiece. An inner member extends in a generally spiral fashion across at least a portion of a distal face of the central body portion. The inner member defines a channel between the

first passage and the at least one second passage. When the tip is place against the skin, a chamber can be formed by the channel and the person's skin.

[0010] In some embodiments, a method of treating a target region on a patient's skin comprises providing a tip including a first aperture and at least one second aperture. At least one inner member on the surface of the tip defines at least one channel between the first aperture and the at least one second aperture. An outer member is disposed on the surface of the tip. The outer member engages the target with the tip. A treatment fluid flows distally through the first aperture region and through the at least one channel. The treatment fluid flows proximally through the at least one second aperture.

[0011] In some embodiments, a tip comprises a skirt portion configured to couple to a handpiece for treating a target on a patient's skin. A central body portion is coupled to the skirt portion and includes a mounting region substantially opposite the skirt portion. The mounting region configured to receive a pad for treating the skin. A first aperture extends through the skirt portion and the central body portion and configured to receive a fluid from the handpiece. At least one second aperture extending through the skirt portion and the central body portion and configured to convey the fluid back into the handpiece.

[0012] In some embodiments, a method of treating a target region of a patient comprises providing a tip including a first aperture, at least one second aperture, and a distal end configured to receive a pad. In some variations, the first pad is attached to the distal end. The tip is engaged with the target region.

[0013] In some embodiments, a manifold system comprises a body portion configured to receive releasably at least two bottles. The manifold is configured so that it can be coupled to a console. The console includes a handpiece for treating skin. At least one elongate member is in communication with a pump and configured to extract a fluid from one of the at least two bottles. At least one switch is configured to permit or inhibit a flow of the fluid from one of the at least two bottles through the pump. In some variations, the elongate member is dimensioned to fit within one of at least two bottles to draw fluid out of the bottle.

[0014] In some embodiments, a method of treating a target region on a patient's skin comprises engaging a tip with the patient's skin such that an effective amount of skin is

removed by the tip. In some variations, the tip is a dry tip. After removing an effective amount of skin, another tip (e.g., a wet tip) engages the patient's skin such that an effective amount of skin is removed by the tip. In some variations, acid is delivered out of the wet tip to facilitate skin removal. In some variations, the wet tip includes a first aperture, at least one second aperture, at least one inner member on the surface of the tip defining at least one channel between the first aperture and the at least one second aperture, and an outer member on the surface of the tip. In some variations, treatment fluid flows outwardly along the channel. In some variations, treatment fluid flows inwardly along the channel. In some variations, the wet tip comprises an abrasive pad.

[0015] In some embodiments, a method of treating a target region on a patient's skin comprises engaging a first skin treatment tip with the patient's skin. A first material is delivered out of the first skin treatment tip to a target region. A second skin treatment tip engages the target region while the first material effectively facilitates exfoliation with the second skin treatment tip. In some variations, the first material comprises an acid, hydrator, and combination thereof. In some variations, the first skin treatment tip is configured to remove skin at a different rate than the second skin treatment tip. In some variations, the first skin treatment tip is configured to exfoliate at a higher rate than the second skin treatment tip. In some variations, material is delivered out of the second treatment tip to the target region of the patient's skin.

[0016] The apparatus for treating skin can dispense treatment material that is held in containers, such as bottles, bags, pouches, or other suitable structures for holding and storing material. These containers can be non-refillable or refillable. The treatment material can be delivered by gravity feed, pumps, or suction devices. The manifold system can be used to control fluid flow from a plurality of containers to one or more handpieces.

Brief Description of the Drawings

[0017] Having thus summarized the general nature of the invention, certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the figures that follow.

[0018] Figure 1 is a perspective view of one embodiment of a skin treatment system.

[0019] Figure 2A is a perspective view of one embodiment of a handpiece assembly for use with the skin treatment system of Figure 1.

[0020] Figure 2B is a side elevational view of the handpiece assembly of Figure 2A.

[0021] Figure 3 is a longitudinal cross-sectional view of the handpiece assembly of Figure 2B. The handpiece assembly is engaging a person's skin.

[0022] Figure 4 is a perspective view of another embodiment of a handpiece assembly.

[0023] Figure 5A is a perspective view of one embodiment of a tip that can be coupled to a main body of a handpiece assembly to treat a person's skin.

[0024] Figure 5B is a top elevational view of the tip of Figure 5A.

[0025] Figure 5C illustrates a bottom elevational view of the tip of Figure 5A.

[0026] Figure 5D is a cross-sectional view of the tip of Figure 5B taken along the line 5D-5D.

[0027] Figure 6A is a perspective view of a tip in accordance with another embodiment.

[0028] Figure 6B is a top elevational view of the tip of Figure 6A.

[0029] Figure 6C is a bottom elevational view of the tip of Figure 6A.

[0030] Figure 6D is a cross-sectional view of the tip of Figure 6B taken along the line 6D-6D.

[0031] Figure 7A is a perspective view of a tip in accordance with another embodiment.

[0032] Figure 7B is a top elevational view of the tip of Figure 7A.

[0033] Figure 7C is a bottom elevational view of the tip of Figure 7A.

[0034] Figure 7D is a cross-sectional view of the tip of Figure 7B taken along the line 7D-7D.

[0035] Figure 8A is a perspective view of yet another embodiment of a tip for treating a person's skin.

[0036] Figure 8B is a top elevational view of the tip of Figure 8A.

[0037] Figure 8C is a bottom elevational view of the tip of Figure 8A.

[0038] Figure 8D is a cross-sectional view of the tip of Figure 8B taken along the line 8D-8D.

[0039] Figure 9A is a perspective view of still another embodiment of a tip that can be coupled to a main body of a handpiece assembly.

[0040] Figure 9B is a top elevational view of the tip of Figure 9A.

[0041] Figure 9C is a bottom elevational view of the tip of Figure 9A.

[0042] Figure 9D is a cross-sectional view of the tip of Figure 9B taken along the line 9D-9D.

[0043] Figure 10A is a perspective view of another embodiment of a tip for treating a person's skin.

[0044] Figure 10B is top elevational view of the tip of Figure 10A.

[0045] Figure 10C is bottom elevational view of the tip of Figure 10A.

[0046] Figure 10D is a cross-sectional view of the tip of Figure 10B taken along the line 10D-10D.

[0047] Figure 10E is a perspective exploded view of the tip of Figure 10A, wherein a pad is spaced from a tip main body.

[0048] Figures 11A-11E are cross-sectional views of inner members that can be used to exfoliate skin.

[0049] Figure 12 is a perspective view of a bottle for use with the skin treatment system of Figure 1.

[0050] Figure 13A is a cross-sectional view of one embodiment of a bottle spaced from an insertion tip assembly.

[0051] Figure 13B is a cross-sectional view of the bottle of Figure 12A coupled with the insertion tip assembly.

[0052] Figure 14A is a cross-sectional view of a closure and a bottle.

[0053] Figure 14B is a cross-sectional view of the closure and bottle of Figure 14A when assembled.

[0054] Figure 15A is a perspective view of one embodiment of a manifold system holding a plurality of bottles.

[0055] Figure 15B is a cross-sectional view of the manifold system of Figure 15A taken along the line 15B-15B of Figure 15A.

[0056] Figure 15C is a cross-sectional view of the manifold system of Figure 15A taken along the line 15C-15C of Figure 15A.

[0057] Figure 15D is a cross-sectional view of the manifold system of Figure 15C wherein the bottle has been removed.

[0058] Figure 15E is a cross-sectional elevational view of the manifold system.

[0059] Figure 16 is a perspective view of another embodiment of a skin treatment system.

[0060] Figure 17 is a cross-sectional view of a fluid line of the skin treatment system of Figure 16 taken along the line 17-17.

[0061] Figure 18 is a side elevational view of a handpiece assembly with a removable cartridge.

[0062] Figure 19 is a side elevational view of the handpiece assembly and removable cartridge of Figure 18, the cartridge is shown removed from the handpiece assembly.

Detailed Description of the Preferred Embodiment

[0063] Figure 1 illustrates a skin treatment system 10 that can be used to perform one or more treatments on a person's skin. The illustrated skin treatment system 10 includes a console 12 and a handpiece assembly 18 connected to the console 12 via a line 20. A manifold system 24 can control the flow of treatment material from containers 26 into and through the line 20. The treatment material can be discharged out of the handpiece assembly 18 to treat a person's skin. The skin treatment system 10 can be used at a hospital, health care physicality, residences, or any other suitable location.

[0064] As explained in more detail below, the handpiece assembly 18 is applied to the target area of the patient to perform skin treatment(s). As used herein, the term "skin treatment" is a broad term and includes, but is not limited to, skin removal, skin abrasion (e.g., dermabrasion, microdermabrasion, etc.), ablating or slicing skin (preferably a thin layer of skin), stimulation (including thermal, mechanical, electrical, and/or chemical stimulation), mesotherapy, isophoresis, light therapy, vacuum therapy, and the like. Preferably, the

handpiece assembly 18 administers a treatment material from at least one of the containers 26 through the line 20 to the target area of the skin while the handpiece assembly 18 engages the skin.

[0065] As used herein, the term “treatment material” is a broad term and includes, but is not limited to, medicament, a substance tending to flow or conform to the outline of its container such as fluid, gas, liquid (e.g., serums, water, saline, etc.), gel, fluidized material, additives, and/or a plurality of fine solids. The general term “fluid” is used throughout synonymously with the term “treatment material” and is to be given the same broad definition. The handpiece assembly 18 can preferably massage, abrade, ablate, or otherwise treat the target skin area while also applying a treatment material to the patient. In certain embodiments, the treatment material and tip of the handpiece 18 can work in combination for an effective and rapid skin treatment. Additionally, any number of “dry” and “wet” tips can be used alone or in combination for treatment flexibility.

[0066] With continued reference to Figure 1 the line 20 is configured to provide fluid communication between the containers 26 and the handpiece assembly 18. The line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18. In certain embodiments, the line 20 includes a supply line and a waste line for delivering and returning material, respectively, as detailed below.

[0067] The distal end 22 of the line 20 is connected to the handpiece assembly 18. Preferably, the line 20 includes a filter 28 that removes contaminants or impurities from the treatment material passing through the line 20. In other embodiments, the filter 28 is located in the console 12 or the manifold system 24. The console 12 can be connected to a power source such as an AC outlet. The power source can power the handpiece assembly 18 and/or other components of the skin treatment system 10, such as, for example, pumps, valves, and the like.

[0068] In the illustrated embodiment, the console 12 comprises four casters 33 to allow for easy movement, for example, from one treatment room to another treatment room. In such an embodiment, the console 12 can be conveniently rolled on a support surface. Other means of transportation can also be employed or the console 12 can be stationary. In some embodiments, the console 12 is portable for convenient transport.

[0069] The illustrated containers 26 of Figure 1 are preferably releasably coupled to the manifold system 24. The manifold system 24 can deliver treatment material from the containers 26 to the line 20 as mentioned above. In certain embodiments, the console 12 has a user input device 32 for selecting a treatment material to be passed through the line 20 to the handpiece assembly 18. During some skin treatment procedures, treatment materials from multiple containers 26 are sequentially or simultaneously applied to the patient's skin during a "wet" mode of operation. Alternatively, the skin treatment system 10 can be used to deliver a single treatment material to the patient's skin. In some embodiments, the console 12 can be used for a "dry" mode of operation. That is, the console 12 can be used to exfoliate skin, for example, without delivering little or substantially no treatment fluid. The skin treatment system 10 can thus provide flexibility in selecting a treatment plan.

[0070] Multiple handpieces assemblies 18 and/or tips 34 can be used during a single skin treatment procedure in a wet and/or dry mode of operation. For example, a first handpiece assembly 18 may be employed to treat a patient's face and neck while a second handpiece assembly 18 may be employed to treat other larger areas of the patient's body. Thus, different handpieces 18 can be used to treat different regions of a person's body. The configurations of the handpieces 18 and tips can be selected based on the treatment material to be applied, desired interaction with the patient's skin, size of treatment area, skin condition, and the like.

[0071] With reference to Figures 2A and 2B, the handpiece assembly 18 includes a main body 30 and a tip 34. The handpiece assembly 18 can be conveniently held within the hand of a user so that the user can place the tip 34 in operative engagement with a person's skin. The user is typically an aesthetician (e.g., an aesthetician allowed to perform microdermabrasion), doctor, and other medical personnel, such as a physician assistant and nurse practitioner. In some cases, the user is the person whose skin is being treated.

[0072] The main body 30 has contoured portions 70 at its distal end 36 so that the user can comfortably grip the handpiece assembly 18 during use. The main body 30 can have other designs to provide a comfortable grip. Figure 2A illustrates an embodiment in which the main body 30 is substantially flat on two opposing sides. Figure 4 illustrates an embodiment in which the main body 30 is generally cylindrical.

[0073] As noted above, the tip 34 can be pressed against a patient's skin to perform a skin treatment. The distal end 102 of the tip 34 may be angled with respect to the handpiece assembly 18 to increase the contact area with the patient's skin without enlarging the handpiece assembly 18 for an ergonomic and comfortable design. The angled tip 34 can lay flat on the skin while the main body 30 is angled to the skin. The angle between the face of the distal end 102 and the longitudinal axis of the handpiece assembly 18 can be selected based on the desired size of the face of the distal end 102. In alternative embodiments, the face of the distal end 102 is generally perpendicular to the longitudinal axis of the main body 30.

[0074] The tip 34 can be permanently or temporarily coupled to the distal end 36 of the main body 30. In some embodiments, the tip 34 is disposable. As used herein, the term "disposable," when applied to a system or component (or combination of components), such as a tip, container, or pad, is a broad term and means, without limitation, that the component in question is used a finite number of times and then discarded. Some disposable components are used only once and then discarded. Other disposable components are used more than once and then discarded. In some embodiments, the tip 34 is removably coupled to the main body 30 such that the tip may be removed from the main body 30 and thrown away to avoid cross-contamination. In other embodiments, the tip 34 is a reusable tip that can be cleaned, for example by autoclaving, after each use. The tip 34 can thus be used for any number of procedures as desired.

[0075] With reference to Figures 2A and 2B, the proximal end 40 of the main body 30 is operatively connected to the line 20. In the embodiment illustrated, the line 20 includes an output line 50 for removing waste from the handpiece assembly 18 and an input line 52 for delivering treatment material to the handpiece assembly 18. The proximal end 40 of the main body 30 includes a plurality of connectors 44, 46, each connected to one of the conduits 50, 52. The illustrated input line 52 is connected to the connector 46, and the output line 50 is connected to the connector 44.

[0076] The input line 52 delivers treatment material from at least one of the containers 26 to the connector 46. The fluid then flows through the main body 30 and ultimately to the tip 34. As shown in Figure 3, the main body 30 comprises a plurality of

lumens 90, 92 in a fluid communication with the tip 34. Fluid from the input line 52 can flow through the input lumen 92 to the tip 34. The fluid then flows out of the tip 34 to a target skin area. The fluid is then trapped in the space 100 between the skin 80 and the tip 34. To remove the fluid, the fluid flows proximally through the lumen 90 to the output line 50. The fluid passes through the output line 50 and into the console 12. As such, fluid can continuously or intermittently flow through the handpiece assembly 18.

[0077] To treat the person's skin 80, the handpiece assembly 18 can also be moved relative to the skin 80 such that the tip 34 maintains engagement with the skin 80. The illustrated tip 34 is configured to massage the skin 80 while also providing fluid communication with the skin 80. As detailed below in connection with Figures 5A through 10, the tip can include sharp planing blades, blades (e.g., razor blades), raised sharp areas, molded posts, grits, or other structures for treating skin, as detailed below.

[0078] When the tip 34 and treatment material are used in combination, the handpiece assembly 18 preferably exfoliates dead skin cells and extracts impurities by applying a vacuum while simultaneously bathing the healthy underlying skin with active treatment material. The active treatment material can facilitate cleansing, exfoliating, hydrating, and/or provide residual antioxidant protection. The treatment material and tip 34, alone or in combination, can effectively and rapidly treat the target skin area. The waste material, including the used treatment material, removed skin, and/or grit, can then be drawn back through the tip 34, the main body 30 via lumen 90, and into the connector 44. The waste then flows into the output line 50 for subsequent disposal, as detailed below in connection with Figure 4.

[0079] In some embodiments, including the illustrated embodiment of Figure 3, the tip 34 has a tip connector 98 (see Figures 5C and 5D) that mates with the lumen 92. The tip 34 can provide fluid communication from the tip connector 98 to the space 100 via a through-hole 122. One or more through-holes 114 define fluid passageways through the tip 34 between the space 100 and the intermediate chamber 116.

[0080] The intermediate chamber 116 can be interposed between the through-holes 114 and the lumen 90. The intermediate chamber 116 is preferably defined by the distal face 43 of the main body 30 and the proximal face 41 of the tip 34. The intermediate

chamber 116 can provide equalization of fluid between the tip 34 and the body 30. As such, a generally equal vacuum is applied to both through-holes 114. The fluid can flow through the through-holes 114, into the intermediate chamber 116, and then into the lumen 90. In some embodiments, however, the fluid flows directly from the through-holes 114 to the lumen 90 without passing through an intermediate chamber 116.

[0081] The tip 34 can have one or more sealing members to form a fluidic seal between the tip 34 and the main body 30. The illustrated main body 30 includes a sealing member 47 that engages the inner surface of the skirt 64 of the tip 34. The sealing member 47 can be a compliant member comprising rubber, polymer, plastic, or other suitable material for forming seals. In some embodiments, the sealing member 47 is an O-ring made of rubber.

[0082] With continued reference to Figure 3, during use, treatment material can flow distally through the lumen 92 into the through-hole 122. The treatment material then proceeds through and out of the through-hole 122 into the space 180. Preferably, the treatment material spreads radially outward to the peripheral through-holes 114. The material can then flow through the through-holes 114 into the lumen 90 for subsequent removal.

[0083] In alternative embodiments, the fluid flows in the opposite direction. That is, the line 50 delivers fluid through the lumen 90 into the tip 34. The fluid flows through the intermediate chamber 116 and the through-holes 114. The fluid then flows to the chamber 100 and inwardly through the tip connector 98 to the lumen 92. The fluid proceeds proximally along the lumen 92 and ultimately into the line 52.

[0084] In yet another embodiment, the handpiece assembly 18 comprises two or more input lumens 90. Such a design allows mixing of two or more treatment materials within the handpiece assembly 18 or space 100, which would be useful for treatments with fluids that react or are unstable or degrade when stored or mixed.

[0085] As depicted in Figure 4, the handpiece assembly 18 can optionally include a controller 60 that is configured to control the fluid flow out of the tip 34. The illustrated controller 60 can be operated to increase or decrease the flow rate of treatment fluid out of the tip 34. Alternatively or additionally, the controller 60 may control the flow rate of waste fluid flowing through the handpiece assembly 18 to the output line 50. When control of the

waste treatment fluid and waste fluid is independent, the detention time of the fluid in the tip 34 may be adjusted as desired.

[0086] The illustrated controller 60 is a generally cylindrical body that is pivotally connected to the main body 30. Figure 4 illustrates an embodiment in which the controller 60 is recessed into and partially hidden by the main body 30, although in other embodiments the controller 60 may encircle the main body 30. The controller 60 may include textured grooves to provide for easier manipulation. In some embodiments, the controller 60 is located near the distal end 36 of the handpiece assembly 18 proximal or distal of the contoured portion 70. The type and configuration of the controller 60 can be selected based on the design of the handpiece assembly 18. The controller 60 can also be a rotatable knob or handle, digital controller, and the like.

[0087] The handpiece assembly 18 can also include one or more flow rate controllers within the main body 30 that cooperate with the controller 60 to adjust the fluid flow out of the tip 34. For example, the controller 60 may comprise a flow control valve such as a globe valve, butterfly valve, needle valve, or variable orifice. Other types of flow rate controllers can also be used, such as an electrically controlled solenoid valve. In embodiments where the fluid flow is electronically controlled, the valve system may alternatively be located in the console 12 or manifold system 24. Separate devices can also be used to control the flow of treatment material. For example, clamps, pinch valves, or other suitable devices can be used to control fluid flow through the lines 50, 52.

[0088] Various types of tips 34 can be used with the handpiece assemblies 18 illustrated in Figures 1 to 4. Figures 5A through 10E illustrate embodiments, for example, of tips 34 that can be used with these handpiece assemblies 18. These tips 34 can be interchangeable to provide maximum treatment flexibility.

[0089] As shown in Figures 5A through 10E, the tip 34 comprises the skirt 64 and a tip main body 66 extending outwardly therefrom. The skirt 64 is preferably configured to provide a gripping surface suitable for applying leverage or force sufficient to remove the tip 34 from the main body 30. In some embodiments, the skirt 64 includes internal threads such that it can be mechanically coupled to external threads on the distal end 36 of the main body

30. In some embodiments, the tip 34 can be press fit onto the main body 30. Frictional forces can retain the tip 34 to the main body 30.

[0090] With respect to Figures 5A through 7, the tip 34 comprises an outer member 120 and an inner member 124. The outer member 120 preferably defines the periphery of the distal end 102 of the tip 34. When the tip 34 is placed against skin, the outer member 120 can inhibit fluid flow between the tip 34 and the skin and define the outer portion of the space 100.

[0091] The inner member 124 is preferably spaced from the outer member 120 to define one or more channels. The illustrated outer member 120 defines a continuous channel 140 that extends outwardly from the central through-hole 122 towards at least one of the outer through-holes 114. The inner member 120 can form the sidewalls of the channel 140. Any suitable configuration of channels 140 can be used to provide fluid flow along a flow path. The illustrated channels 140 have a somewhat U-shaped axial cross-sectional profile, as depicted in Fig. 8A. The channel 140 can have a V-shaped, curved, or any other suitable cross sectional profile. A flow path between the through-holes in the tip 34 can be defined at least in part by the channels.

[0092] The spiral-like pattern of the inner members 124 in Figures 5 through 7 varies. For example, the inner member 124 in Figure 5 extends about a longitudinal axis 143 of the tip 34 approximately one and a half times, the inner member 124 in Figure 6 extends about the tip 34 approximately two and a half times, and the inner member 124 in Figure 7 rotates about the tip 34 approximately one and three quarters times. In some embodiments, the inner member 124 subtends an angle of about 70°, 135°, 180°, 210°, 225°, 270°, 315°, 360°, and angles encompassing such ranges. In yet other embodiments, the inner member 124 subtends an angle of about 405°, 450°, or 495°. The tightness of the spiral in combination with the location and number of through-holes 114 affects the detention time of the fluid in the channel 140. Generally, a tighter spiral results in a longer the pathway (i.e., the length of the channel 140) from delivery through-hole 122 to the return through-holes 114. Fluid traveling down the longer pathway is in contact with the person's skin 80 for a longer period of time. Thus, tighter spirals lead to increased contact time between the fluid and the skin 80. These longer contact times can increase the effectiveness of the fluid

because the skin can absorb an adequate amount of active ingredients of the treatment material. Fluid retention time on the patient's skin can be increased to increase hydration, serum retention, and the like. Shorter pathways can be used to reduce contact time between the fluid and the patient's skin. In some embodiments, for example, the tip 34 of Figures 5A to 5D has a relatively short pathway to limit absorption of fluids, achieve relatively high flow rates, and the like.

[0093] Additionally, the inner members 124 can be configured to remove tissue. The inner member 124 can be an abrasive member designed to remove tissue when the inner member 124 slides along a person's skin. The user may select a tip 34 based on the appropriate detention time and abrasiveness for the treatment being applied. For example, the tip 34 illustrated in Figure 7 will provide less abrasion than the tip illustrated in Figure 6, but the tip 34 illustrated in Figure 7 will provide a longer detention time than the tip 34 illustrated in Figure 5.

[0094] The illustrated tip 34 includes a generally continuous inner member 124 that extends from near the through-hole 122 towards at least one of the through-holes 114. In other embodiments, the tip 34 can have a plurality of inner members 124. For example, the inner members 124 can be linear, curved, and may be continuous or discontinuous.

[0095] The handpiece assembly 18 can be moved while the spiral-like inner member 124 engages the patient's skin. The movement of the handpiece assembly 18 can increase the effectiveness of the treatment material expelled out of the tip 34. In some embodiments, for example, the tip 34 can be used with a lifting treatment material that facilitates extractions of, for example, sebum, blackheads, skin, or other substances (e.g., oils, dead skin, etc.). The lifting treatment extraction producer can unclog pores to improve the treated skin's overall appearance. To facilitate extractions, the handpiece assembly 18 can be twisted or rotated while the tip 34 is pressed against the patient's skin. The twisting action and the lifting treatment material can work in combination for effective extractions. In alternative embodiments, a handpiece assembly 18 can also be used without a lifting treatment material for extractions by employing the twisting motion.

[0096] In certain embodiments, the spiral-like tip 34 massages the skin 80. In other embodiments, the spiral-like tip 34 ablates the skin 80. For example, the inner

members 124 may act as blades to cut thin layers from the skin 80 when the user twists the handpiece assembly 18. Twisting the handpiece assembly 18 causes the tip 34 to rotate about the twisting axis, rotating the sharp inner members 124 against the skin 80, which causes ablation. Thin layers of skin can thus be removed by the handpiece assembly 18. Additionally or alternatively, the spiral-like tip 34 may plane along skin when a fluid is applied to the skin. The planing tip 34 can remove a thin layer of the skin (e.g., the stratum corneum, preferably hydrated stratum corneum). Accordingly, the user can use the handpiece assembly 18 to remove a particular amount of skin.

[0097] A vacuum can be applied by the handpiece assembly 18. For example, the console 12 can have a pump that applies a vacuum via the output line 52. The negative pressure draws waste material into the through-holes 114 and out of the handpiece assembly 18. When the tip 34 engages the patient's skin, the vacuum can draw the skin against the tip 34 to enhance the effectiveness of the inner members 124. The vacuum can be increased or decreased to increase or decrease, respectively, for example, frictional forces, depth of cutting, amount of abrasion, and the like. To rapidly remove skin, a strong vacuum can be applied to the person's skin so that the skin is pulled against the inner member 124. The vacuum can also facilitated removal of the waste fluid captured between the tip 34 and the patient's skin. A vacuum can also be used in combination with the tips illustrated in Figures 1-10E. The vacuum can also be varied based on the thickness, compliance, and other properties of the skin surface

[0098] The tip 34 can have any suitable number of through-holes 114, 122 to achieve the desired fluid flow between the skin 80 and the tip 34. For example, Figure 5A to 5D illustrate an embodiment with two through-holes 114. The number of through-holes 114, 122 can be chosen based on the cross-sectional areas of the through-holes 114, 122 and the expected flow rate of the fluid through the channel 100. Preferably, one end of through-holes 114 is positioned between the inner member 124 and the outer member 120. In some embodiments, including the embodiments illustrated in Figures 5A through 7, the through-holes 114 are positioned generally midway between the outer member 120 and inner member 124.

[0099] The tips can also have one or more energy sources for delivering energy to the skin. Radiant energy, heat, and the like can be delivered to the skin by the tips. The tip 34 illustrated in Figures 6A to 6D has a pair of energy sources 151 in the form of LEDs. When the tip 34 is proximate the patient's skin, the LEDs 151 can deliver a desired amount of energy to the skin. The illustrated tip 34 has four LEDs; however, any number of LEDs can be employed.

[0100] In alternative embodiments, the tips can carry deployable material. The structure 151 can be in the form of a cavity or pocket that contain and carry material that is released when it engages the treatment fluid. The material in the cavities 151 can be made of any of the treatment materials disclosed herein, and can be in a solid form. For example, the cavities can hold lubricant or soap that is released when the tip is applied to skin.

[0101] Figures 8A through 8D illustrate another embodiment of a tip 34 when the inner member 124 includes a ring with perforations 140 that provide fluid communication between the through-hole 122 and through-holes 114. A space 100 can be defined between the inner member 124, perforations 140, and outer member 120 when the tip 34 is in operative engagement with the skin 80. Figure 8C illustrates an embodiment with eight through-holes 114. In the embodiment illustrated in Figures 8A through 8D, the inner member 124 forms recessed regions 171, allowing for a larger area of fluid contact with the skin 80 than the tips 34 illustrated in Figures 5 through 7.

[0102] Figures 9A through 9D illustrate another embodiment of a tip 34 comprising an outer member 120 and an array of protruding inner members 124. A recessed region 191 is defined between the inner members 124 and the outer member 120. The inner members 124 of Figures 9A to 9D can be posts that are similar to the inner members described above. The post 124, for example, can have relatively sharp edges. These edges can be used to remove skin. In some embodiments, the inner members 124 can have relatively sharp planing blades. The tip 34 illustrated in Figures 9A through 9D allows for more freedom of movement of the treatment fluid. The protruding inner members 124 preferably abrade the skin differently than the tips 34 illustrated in Figures 5A through 8. Rather than being able to ablate large sections of the skin 80 like a blade, as the tips 34 in

Figures 5A-8 can do in certain embodiments, the plurality of protruding inner members 124 can ablate or roughen a plurality of smaller sections of the skin 80.

[0103] The protruding member 124 can optionally contain treatment material. For example, the protruding members 124 can be generally cylindrical members having a passageway or chamber 127 that holds treatment material. Thus, fluid can be used in combination with treatment material coupled to the tip 34.

[0104] With reference to Figures 5A through 9, the inner member 124 preferably has a height from the distal surface that is generally less than the height of the outer member 120. In some non-limiting embodiments, the height of the inner member 124 is less than 90%, 70%, 60%, 50%, and ranges encompassing such percentages of the height of the outer member 120. However, in other embodiments, the inner member 124 has a height that is generally greater than the height of the outer member 120. For example, the inner member 124 can have a height that is 10%, 20%, 30%, 40%, 50% greater than the height of the outer member 120. The inner member 124 can thus protrude from the tip 34. A skilled artisan can select a desired height of the inner member 124 and/or the outer member 120 to achieve the desired interaction with the person's skin 80.

[0105] Figures 10A through 10E illustrate another embodiment of a tip 34 comprising an outer member 120 and a pad 128. Figure 10E depicts the pad 128 removed from the tip 34. The tip 34 preferably has a mounting surface 227 that is surrounded by the outer member 120. The pad 128 can be permanently or temporarily coupled to the mounting surface 227.

[0106] The pad 128 preferably has a distal surface 224 configured to treat a person's skin. In some embodiments, the pad 128 is a disposable pad that comprises treatment material attached thereto. For example, the pad 128 may comprise vitamins, moisturizers, antioxidants, and the like. Preferably, the pad 128 comprises an adhesive proximal side and a distal side 224 including an abrasive surface. The abrasive surface can have grit, a plurality of members (e.g., members similar to the inner members 124 described above), or the like. The pad 128 can be permanently coupled to the mating surface 227 so that the tip 34 can be used for an extended length of time, or for multiple treatments. In alternative embodiments, the tip 34 is removable for maximum flexibility in selecting pad

abrasiveness, and also allows the user to make changes to the tip 34 without changing the tip 34 in its entirety. The grit rating of abrasive surface of the distal surface 224 can be selected based on the desired rate of skin removal.

[0107] The illustrated pad 128 is generally elliptical and planar. In alternative embodiments, the pad 128 can be polygonal, circular, or have any other shape as desired. The pad 128 can have cutouts 225 that can match the through-holes 114, 122. The cutouts 225 can be aligned with the through-holes 114, 122 when the pad 128 is coupled to the mounting surface 227 of the tip 34, as shown in Figures 10A to 10D. The illustrated mounting surface 227 defines a plurality of tip flow channels 229 extending between the through-holes 114, 122. When the tip 34 is assembled, fluid can flow along the channels 229 between the main body 66 and the pad 128.

[0108] Various types of adhesives can be used to temporarily or permanently couple the pad 128 to the mounting surface 227. As used herein, the term “adhesive” is a broad term and includes, but is not limited to, coupling agents, glues, bonding materials, or the like. In some embodiments, for example, waterproof pressure sensitive adhesives are used for releasably coupling the pad 128 to the mounting surface 227. In some embodiments, the pad 128 can be permanently coupled to the mounting surface 227. For example, the pad 128 can be bonded or fused to the main body 66. Additionally or alternatively, snap fittings, fasteners, or other coupling structures can be used to mount the pad 128.

[0109] The tip 34 described above can be used for wet or dry modes of operation. As such, the tip 34 can be used for wet exfoliation or dry exfoliation. In some embodiments, the tip 34 is used in a dry mode to remove a desired amount of skin. After removing a desired amount of skin, the tip 34 can be used in a wet mode on the same or different area of the patient's skin. During wet mode, fluid can be passed out of the tip 34 onto the patient's skin. The wet tip 34 can exfoliate, hydrate, and/or perform other types of treatments. Alternatively, the tip 34 can be used in a wet mode and then a dry mode. The sequence of wet and dry modes of operation can be selected based on the type of tip, treatment material, skin condition, and the like.

[0110] Although the handpiece assemblies are primarily discussed with respect to use with treatment material, the handpiece assemblies can be used without treatment material,

i.e., the handpieces can be used in a dry procedure. Dry procedures can be used for non-hydration procedures and may require less post-procedure clean up.

[0111] Various fabrication techniques can be employed to make the tips 34 as mentioned above in connection with Figures 11A-11E. In some embodiments, the tips 34 are formed through a molding process, such as an injection or compression molding process. The tips 34 of Figures 5A to 5D, for example, can be monolithically formed through an injection molding process. Alternatively, the tip 34 of can have a multi-piece construction, if desired. The tips 34 can be made of polymers, rubbers, metals, or other suitable materials.

[0112] The tips 34 can also be fabricated in a multi-step process. For example, the main body 66 and skirt 64 can be formed in a single process. A textured surface (e.g., pad, inner members 124, etc.) can be applied to the main body 66 in a subsequent process. The textured surface can be formed by cutting, embossing, adding material (e.g., a pad, adhesive grit, etc.), a roughening implement, stamping process, or other suitable texturing means.

[0113] The tips can have associated treatment materials, including, for example, a medicament. As used herein, the term “medicament” is a broad term and includes, without limitation, growth agents, growth factors or hormones, growth inhibitors, serums, treatment material, cleaners, vitamins, exfoliators, lubricants, or other substances that can be used to treat a patient’s skin. The medicament can be associated with the tip 34 by imbedding, overlaying, coating, impregnation, co-mixing, absorption, or other suitable means for associating the medicament with the tip 34. The medicament can be hardened so that it can further enhance massaging and/or abrasion. In some embodiments, the medicament forms hardened grit that can be imbedded on the surface of the tip 34. The grit can work in combination with the inner members 124 to treat a person’s skin. If a fluid is used, the fluid can facilitate the release of the medicament from the tip 34. In some embodiments, the medicament comprises or more bioactive substances, such as antibiotics, substances for accelerating the healing of the wound, cell proliferation agents, and the like. Such bioactive substances may be desirable because they contribute to the healing of damaged or removed skin, as well as reducing the likelihood of infection.

[0114] Figures 11A to 11E illustrate different cross-sections of inner members that can be used with the tips illustrated in Figures 1-10E. The inner member 124 of Figure 11A has generally sharp tip 253 for removing tissue. The tip 253 can have any suitable configuration for removing tissue from a patient. Figure 11B illustrates an inner member 124 that has a pair of cutting edges 253 and a generally trapezoidal shape. Figure 11C illustrates an inner member 124 that has a surface treatment 255 for treating a person's skin. The surface treatment 255 can be serrations, grooves, grit, roughed surface, protrusions, and the like. The type of surface treatment 255 can be selected based on the procedure to be performed. Figure 11D illustrates another inner member 124 having a pair of cutting edges 253. The cutting edges 253 are spaced from each other and protrude outwardly. The central portion 257 is generally V-shaped; however, the central portion 257 can have other configurations. For example, Figure 11E illustrates a central portion 257 that has a curved, semi-circular profile. In alternative embodiments, the inner member 124 can have more than two cutting edges.

[0115] The inner members 124 of Figures 11A to 11E can be formed by a molding process, such as an injection molding process. Additionally or alternatively, the inner members 124 can be formed by a machining process. For example, at least a portion of the inner member 124 of Figures 11D to 11E can be formed through a machining process. In some embodiments, the central portion 257 can be formed by cutting material out of the inner member 124. The fabrication process (e.g., molding, injection molding, compression molding, machining, milling, etc.) can be selected based on the design of the inner members.

[0116] Referring again to Figure 1, the console 12 includes a manifold system 24 that holds containers 26 containing treatment fluids and/or antimicrobial agents. In a preferred embodiment, the console 12 holds four containers 26, three containing different treatment fluids and one containing an antimicrobial agent. In the illustrated embodiment, the largest container 26 holds antimicrobial agent for cleaning and sanitizing the fluid lines of the console 12. The containers 26 can also hold other suitable substances, such as surfactants, disinfectants, sanitizers, and the like, for cleaning and/or sanitizing the skin treatment system 10.

[0117] As shown in Figures 12 and 12A, the container 26 can be a fluid source such as a bottle comprising a body 262, a neck 264, and a closure assembly 266. The neck 264 includes a threaded neck finish and the closure 266 includes a threaded interior surface, allowing it to screw onto the neck 264. The closure 266 can be permanently or temporarily coupled to the neck 264. The illustrated bottle 26 is a non-refillable, disposable bottle. As used herein, the term “non-refillable” is a broad term that includes, but is not limited to, components that cannot be easily refilled with a treatment material. For example, the illustrated non-refillable bottle 26 cannot be refilled without substantial difficulty.

[0118] Bodies 262 of the containers 26 may be formed by stretch blow molding a preform into the desired shape. In other embodiments, the body 262 and a neck 264 can be formed by extrusion blow molding. For example, the bottle of Figure 13A can be formed by extrusion blow molding. The containers 26 can be made of polymers, thermosets, thermoplastic materials such as polyesters (e.g., polyethylene terephthalate (PET)), polyolefins, including polypropylene and polyethylene, polycarbonate, polyamides including nylons, epoxies, and/or acrylics. The material can be virgin or post-consumer/recycled. However, other suitable materials known in the art can also be used.

[0119] In some embodiments, including the illustrated embodiment of Figures 12 and 12B, the closure 266 is welded (e.g., induction welded) to an upper edge 269 of the neck 264. A sealing member 267 can be interposed between the upper edge of the neck 269 and the closure 266. In some embodiments, the sealing member 267 is made out of a conductive metal, such as aluminum, that preferably does not react with the fluid in the bottle 26. In other embodiments, the seal 267 comprises plastic, such as cellophane, polypropylene, or other suitable material, preferably suitable for coupling to the closure 266 and upper edge 269. In some embodiments, the sealing member 267 comprises metal that is at least partially coated with a polymer, such as polypropylene. Induction welding can be used to couple the polypropylene to the closure 266 and neck 264, both of which can also comprise polypropylene.

[0120] Figure 14A illustrates another embodiment of a bottle 26. The closure 266 includes locking members 268 that engage the neck 264, but do not allow removal of the

closure 266 from the bottle 26 when assembled, as shown in Figure 13B. The locking closure 266 may include a sealing member 267, for example as described above.

[0121] In either of the embodiments illustrated in Figures 12 through 14B, the closure 266 may then be sealed with a second closure (not shown), creating multi-piece closures. For example, a screw cap can be threaded onto the external threads 273 at the top end of the closure 266. In these embodiments, the treatment fluid inside the bottle 26 may be accessed by puncturing or otherwise breaking the seal 267, for example with an insertion tip assembly 59 (see Figure 13A).

[0122] The insertion tip assembly 59 has an elongate member 161 that comprises a fluid pick up conduit 62 and lancing tip 64 extending from the distal end of the conduit 62. In the illustrated embodiment, the lancing tip 64 is a tubular member having a somewhat sharp distal end. To access treatment fluid in the bottle 26, the lancing tip 64 can be inserted into the closure passageway 73 of the closure 266. The lancing tip 64 can be advanced through the passageway 73 until it breaks the sealing member 267. The elongate member 161 can be sufficiently rigid such that it can break the sealing member 267 without buckling. The elongate member 161 can comprise metal, polymers, plastics, or any suitable material.

[0123] The fluid pick up conduit 62 and lancing tip 64 can be slid through the passageway 73 until the stop 91 is spaced from the upper edge of the closure 266. In alternative embodiments, the insertion tip assembly 59 can be slid through the passageway 73 until the stop 91 contacts the upper edge of the closure 266, as shown in Figure 12B. After the insertion tip assembly 59 and bottle 26 are assembled, as shown in Figure 12B, the treatment material can be draw upwardly through the lancing tip 64 and the fluid pick up conduit 62. The treatment material can flow through a passageway of the insertion tip assembly 59 and to the manifold assembly 24.

[0124] In certain embodiments, the treatment fluid applied from the containers 26 may be selected from the console 12 for a particular treatment or skin type. In one embodiment, the treatment fluid may comprise a skin rejuvenation serum. Skin rejuvenation serum cleans the skin 80 deeply while softening sebum and impurities to aid in extractions. Skin rejuvenation serum also assists in dislodging dead cells for extraction and exfoliation by the tip 34 as well as providing residual hydration that aids in firming and smoothing fine

lines, resulting in clean, refined, and ultra-moisturized skin 80. Preferably, a skin rejuvenation treatment serum is active-4™, available from Edge Systems Corp., 2277 Redondo Ave., Signal Hill, CA, 90755, (800) 603-4996. In another embodiment, the treatment fluid may comprise a salicylic acid serum. A salicylic acid serum cleans oily skin deeply while softening sebum and impurities to aid in extraction and exfoliation by the tip 34. Hydration additives in the salicylic acid serum create an ultra-moisturized skin surface, and is blended to remain on the face for the best possible benefit. Preferably, a salicylic acid treatment fluid is beta-hd™, also available from Edge Systems Corp. In yet another embodiment, the treatment fluid may comprise antioxidants. The antioxidant serum is a hybrid that combats free radicals and environmental damage to the cells. The antioxidant serum is formulated with a blend of the most effective antioxidant ingredients. The antioxidant serum is an absorbable, leave-on service that improves the appearance of age signs as well as texture and clarity. Preferably, an antioxidant treatment fluid is antiox-6™, also available from Edge Systems Corp. The treatment fluids may comprise agents known to be beneficial to skin healing and/or hydration including but not limited to glucosamine, laminaria digitata extract, yeast extract, carbamide, lactic acid, sodium lactate, honey extract, pentylene glycol, spirea ulmaria extract, camellia sinensis leaf (white tea) extract, horse chestnut extract, stabilized vitamins A, B1, B6, B12, C, and E, tocopherol, inositol, calcium panthothenate, linoleic acid, rosemarinus officinalis extract, biotin, and aloins such as anthraquinone glycosides, polysaccharides, sterols, gelonins, and chromones.

[0125] A single treatment may comprise the serial use of several treatment fluids from the containers 26. For example, the treatment of acne prone skin may comprise salicylic treatment followed by antioxidant treatment, the treatment of aging skin may comprise skin rejuvenator treatment followed by salicylic treatment followed by antioxidant treatment, the treatment of congestion (e.g., blackheads) may comprise skin rejuvenator treatment followed by salicylic treatment followed by antioxidant treatment, the treatment of damaged skin (e.g., due to medication or smoking) may comprise skin rejuvenator treatment followed by antioxidant treatment, the treatment of skin may comprise skin rejuvenator treatment followed by salicylic treatment followed by antioxidant treatment, the treatment of hyperpigmentation may comprise skin rejuvenator treatment followed by salicylic treatment

followed by antioxidant treatment, the treatment of melasma may comprise skin rejuvenator treatment followed by salicylic treatment followed by antioxidant treatment, the treatment of sensitive skin may comprise skin rejuvenator treatment followed by antioxidant treatment, and the treatment of thin skin may comprise salicylic treatment followed by antioxidant treatment. Alternatively, a single treatment may comprise the parallel use of a combination of treatment fluids from the containers 26, for example using a handpiece with a plurality of input lumens 90 as described above. Treatment time with each treatment fluid is preferably about 2 to 20 minutes, but may be longer or shorter depending on the patient, the tip 34 used, and the treatment itself.

[0126] The treatment materials can be used for acne (e.g., by removing oils, bacteria, etc.), melasma, damaged skin (e.g., sun damaged skin, burns, free radical damage, etc.), extractions, skin lightening and/or brightening, skin lines (e.g., fine lines, wrinkles, creases, etc.), dry skin, and the like. The treatment materials can improve skin elasticity and overall health of the skin. For example, if the skin is damaged, antioxidants can be applied to damaged area. Accordingly, the skin treatment system 10 can be used to improve the health, appearance, and/or function of a person's skin.

[0127] Additionally, the line 20 may be periodically flushed with a fluid (e.g., a antimicrobial fluid, water, etc.) contained in one of the containers 26. Antimicrobial fluids can contain any disinfecting agent compatible with skin including, but not limited to, butylene glycol, phenoxyethanol, and methyl isothiazolinone. Preferably, an antimicrobial fluid is rinseaway™, available from Edge Systems Corp. The line 20 should be flushed with antimicrobial fluid at least at the end of each service day. Flushing with antimicrobial fluid is more important when the system is not used for consecutive days.

[0128] As illustrated in Figure 1, the console 12 comprises the manifold system 24 designed to draw treatment fluid from at least one of the containers 26 based on user selection. The manifold system 24 may include switches 29, each corresponding to one of the bottles. The switches 29 can be used to control fluid flow from the containers 26. The illustrated switches 29 can be used to turn Off/On to permit or prevent fluid flow from the bottles 26. The illustrated manifold system 24 has a switch corresponding to each bottle 26. As such, the switches can be used to independently control fluid flow from each of the bottles

26. In other embodiments, a single switch can be used to control the flow of treatment fluid from more than one of the bottles 26.

[0129] With continued reference to Figure 1, the button 246 can be operated to release a corresponding bottle 26 from the manifold system 24. Figure 15A is front perspective view an embodiment in which the manifold system 24 contains quick-release locks connected to the button 246, wherein the quick-release locks capture the containers 26. As illustrated in Figures 14B and 14C, the quick-release locks 242 engage the closure 266 when the bottle 26 is inserted into the manifold system 24. When the quick-release lock 242 is manually engaged by a user, for example by pulling the button 246, a slide structure 249 surrounding the closure 266 releases, thereby releasing the bottle 26 from the manifold system 24.

[0130] Figure 15E illustrates the slide structure 249 holding the neck 264 of the bottle 26 in an elongated slot 309. The button 246 can be pushed inwardly (indicated by the arrow 313) so that the neck 264 is positioned within the enlarged aperture 317. The bottle 26 can then slide downwardly out of the manifold system 24. The bottle 26 can be replaced with another bottle 26.

[0131] To couple the bottle 26 to the manifold system 24, the closure 266 can be inserted through the aperture 317 of the slide structure 249 when the button 246 is pushed in. Once the closure 266 engages the stop surface 333 (Figure 15C), the spring 247 can push the slide structure 249 until the flange 335 of the bottle 26 rests on the slide structure 249, as shown in Figure 15C. In such a position, the manifold system 24 securely holds the bottle 26. The illustrated slide structure 249 has a sloped portion 269 that can cam along the flange 335 as the button 246 moves outwardly. Accordingly, the slide member 249 can push the closure 266 upwardly until the closure 266 is locked with the manifold 24, as shown in Figure 15C. The quick-release lock 242 is loaded with spring 247 such that the slide structure 249 is biased towards the button 246.

[0132] The manifold system 24 can have a modular design so that it can be removed from the console 12. In some embodiments, the manifold system 24 and associated containers 26 can be removed and transported away from the console 12. Accordingly, the

modular manifold systems can be interchanged to provide treatment flexibility. Alternatively, the manifold system 24 can be permanently mounted to the console 12.

[0133] Figures 15B and 15C illustrate cross-sectional views of the manifold system 24 taken along lines 15B-15B and lines 15C-15C, respectively. Both Figures 15B and 15C show the fluid pick up conduit 62 in operative engagement with the bottle 26 through the seal 267. Suction device(s) is preferably in fluid communication with the fluid pick up conduit 62, and draws fluid out of the bottle 26 through the fluid pick up conduit 62. The fluid can flow through a passageway 161 (see Figure 15C) extending through the pick up conduit 62. The fluid can flow to and through the lumen 171 towards the line 20. If the switch 29 is off, the fluid from one or more of the upstream bottles can flow along the passage 173. The manifold system 24 then directs the fluid into the line 20.

[0134] In certain embodiments, including the embodiment of Figure 1, the console 12 comprises a computer with display 32. In one embodiment, the display 32 is a user input device comprising a touch screen that controls the computer. In other embodiments, the computer may be controlled by input devices such as a keyboard, keypad, mouse, pointing device, or other input device. The computer controls a variety of functions in the console 12. For example, the computer may control the manifold system 24, and thereby the flow of treatment fluids from the containers 26. In one embodiment, the fluid flowing through the line 20 can be changed by pressing a single button on the touch screen display 32. In another embodiment, the computer contains teaching tutorials that are exhibited on the display 32. In yet another embodiment, the user may change program chips within the computer according to treatment and/or patient. In still another embodiment, the computer records patient and treatment data, for example data gathered during treatment.

[0135] The console 12 can also comprise a mechanical system for controlling fluid flow from the containers to the handpiece. One or more pumps, valves, fluid lines, and the like can cooperate to deliver fluid from the containers to the handpiece. The console 12 can be powered pneumatically, electrically, or by any other suitable powering means. The mechanically drive console 12 can have manual controls for controlling fluid flow to the handpiece.

[0136] The console 12 can also comprise additional handpieces suitable for other types of skin treatment. These additional handpieces can be used for pre-treatment or post-treatment in combination with other modalities. For example, the console 12 may include a handpiece for diamond tip abrasion, or “crystal-free” microdermabrasion, as described above. Such a handpiece may be useful for more aggressive treatments, in addition to treatment with the handpiece assembly 18. The diamond tips can range from fine to extra coarse.

[0137] In some embodiments, the console 12 comprises a handpiece including at least one light emitting diode (LED). Light therapy has been shown to improve skin. For example, red light between about 600 and about 700 nanometers and infrared LED light between about 700 and about 1,000 nanometers reduces the appearance of fine lines and superficial hyperpigmentation. For another example, blue LED light at about 430 nanometers improves the appearance of oily and acne-prone skin. Other benefits of light therapy include promotion of collagen production, increased circulation and moisture retention, smoothing of skin texture, and improvement of skin firmness and resilience.

[0138] The console 12 can comprise handpieces for vacuum therapy such as lymphatic drainage and cellulite massage. Vacuum therapy enhances the effects of treatment with the handpiece assembly 18 and LED light therapy. Preferably, the vacuum therapy handpieces are sized appropriately for facial massage and body massage. An example of a multi-modality protocol using a plurality of handpieces comprises diamond tip abrasion, treatment with handpiece assembly 18 and at least one treatment fluid from containers 26, vacuum therapy, red light therapy, and application of sunscreen, for example at a minimum skin protection factor (SPF) of 15. The various modalities may be included and ordered by the user depending on the desired outcome of the overall treatment.

[0139] The console 12 optionally includes any of a plurality of additional features. For example, a digital camera may be used to take pictures of the patient before and after treatment, and the pictures may be stored on the computer. The computer may hold client medical and treatment records. The computer may be connected to a network. The console 12 may store disks. The console 12 may include an ultrasound unit. The console 12 may include a stimulator, such as an electrical stimulator. The console 12 may include an iontophoresis handpiece. The number of additional features is limitless when considering the

range of features that a user may wish to incorporate with the treatment provided by the handpiece assembly 18.

[0140] Figure 16 depicts another embodiment of the skin treatment system 10, which may be generally similar to the embodiment illustrated in Figure 1, except as further detailed below. Where possible, similar elements are identified with identical reference numerals in the depiction of the embodiment of Figure 1.

[0141] The line 20 includes an output line 50 for removing waste from the handpiece assembly 18 and an input line 52 for delivering treatment material to the handpiece assembly 18. A valve 300 can be disposed along the input line 52 to inhibit backflow of treatment material. The console 12 can pump treatment material through the input line 52 to the handpiece assembly 18 when the handpiece assembly 18 is applied to the person's skin, as detailed above. The fluid flow through the input line 52 can be reduced or stopped so that the handpiece assembly 18 can be removed from the patient's skin. The valve 300 can inhibit the flow of fluid through the input line 52 towards the console 12. A desired amount of treatment material can therefore be contained in the handpiece assembly 18 and the section 310 of the input tubing 52 extending between the valve 300 and the handpiece assembly 18. When the handpiece assembly 18 is applied to a patient's skin, a vacuum can be applied to the output line 50. The vacuum can draw the treatment material out of the handpiece assembly 18 without a substantial or noticeable delay.

[0142] In some embodiments, the valve 300 can be a one-way valve, such as a duckbill valve, check valve, or other type of valve for inhibiting fluid flow. In alternative embodiments, the valve 300 can comprises a plurality of valves (e.g., one-way valves, flow regulators, adjustable valves, etc.).

[0143] Figure 17 is a cross-sectional view of the line 20. The input and output lines 50, 52 can have different or similar cross sectional flow areas. The illustrated output line 50 has a passageway 312 with a diameter that is less than the diameter of a passageway 314 of the input line 52. Accordingly, a relatively large slug of treatment material can be stored in the section 310 extending distally from the valve 300 to the handpiece assembly 18. The slug can be quickly delivered out of the handpiece assembly 18 once the handpiece assembly is applied to a patient's skin as detailed above.

[0144] In some embodiments, the section 310 of the output line 50 has a length L greater than 6 inches, 12 inches, 18 inches, 24 inches, and ranges encompassing such lengths. In some embodiments, the section 310 of the output line 50 has a length L greater than 24 inches, 30 inches, 36 inches, and ranges encompassing such lengths. The passageway 312 can have a cross-sectional area that is at least 10%, 30%, 50%, 75%, or 100% greater than the cross-sectional area of the passageway 314. The length L and the diameters of the passageways 312, 314 can be selected based on the desired amount of treatment material to be stored in the line 20, delivery and removal rates.

[0145] Figures 18 and 19 illustrate a modular handpiece assembly 360 having a cartridge 362 containing treatment material. The illustrated handpiece assembly 360 can be used to deliver treatment material from the cartridge 362. The main body 30 can have a pump for pressuring the treatment material. In one embodiment, the fluid control device includes a power supply, such as a battery, which provides power to electrical components (e.g., pumps or valves) of the handpiece assembly 360. The power supply can be a battery that is preferably disposed within the main body 30 of the handpiece assembly 360. In one arrangement, the battery is a rechargeable battery that can be connected to and recharged by an AC power supply, such as a typical residential electrical outlet. Alternatively, the handpiece assembly 360 can be directly powered by an AC power supply. The power supply can provide power to several components of the handpiece assembly 360. For example, the power supply can provide power to a plurality of fluid control devices 330 and/or a flow control unit. A control switch 371 can be used to turn the handpiece assembly 360 Off/On and/or control the output of the handpiece assembly 360.

[0146] In operation, the cartridge 362 can be inserted into the main body 30. The handpiece assembly 360 can be applied to a patient's skin to deliver treatment material from the cartridge 362 to the patient's skin. After delivering a desired amount of treatment material, the cartridge 362 can be separated from the main body 30. The cartridge 362 can be a one-use or multi-use cartridge. For example, the cartridge can be a non-refillable disposable cartridge.

[0147] The tip 34 can also be used to remove hair or perform other skin treatments. For example, the tip 34 can include one or more razor blades and may be

configured to apply a treatment material (e.g., antioxidants, vitamins, serums, growth agents, etc.) to the skin during the shaving process. In such embodiments, the main body 30 can be an elongated handle that is connected to a transversely extending elongate tip 34. In some embodiments, the handpiece assembly can be in the form of a disposable handheld razor. The treatment material can reduce or substantially eliminate problems associated with wet or dry shaving systems. These treatment materials may be applied prior to, during, before, and/or after shaving.

[0148] The articles disclosed herein may be formed through any suitable means. The various methods and techniques described above provide a number of ways to carry out the invention. Of course, it is to be understood that not necessarily all objectives or advantages described may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that the methods may be performed in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objectives or advantages as may be taught or suggested herein.

[0149] Furthermore, the skilled artisan will recognize the interchangeability of various features from different embodiments disclosed herein. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art to perform methods in accordance with principles described herein. Additionally, the methods which are described and illustrated herein are not limited to the exact sequence of acts described, nor are they necessarily limited to the practice of all of the acts set forth. Other sequences of events or acts, or less than all of the events, or simultaneous occurrence of the events, may be utilized in practicing the embodiments of the invention.

[0150] Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for treating skin, the apparatus comprising:
a console having a user input device and a handpiece assembly, which is configured to treat skin;
a fluid line providing fluid communication between the console and the handpiece assembly; and
a manifold system coupled to the console and controlled by the user input device, the manifold system being configured to hold releasably a plurality of fluid sources and deliver fluid from at least one of the plurality of fluid sources to the handpiece assembly.
2. The apparatus of Claim 1, further comprising insertion tip assemblies, each insertion tip assembly having an elongate member configured for insertion into a non-refillable bottle.
3. The apparatus of Claim 2, wherein each elongate member is sufficiently rigid to break a seal of the non-refillable bottle.
4. The apparatus of Claim 1, wherein the handpiece assembly outputs and draws in fluid when a tip of the handpiece assembly is pressed against a person's skin.
5. The apparatus of Claim 1, wherein the treatment comprises abrasion or ablation.
6. The apparatus of Claim 5, wherein the abrasion is at least one selected from the group consisting of dermabrasion, microdermdermabrasion, hydro abrasion, and crystal-free microdermabrasion.
7. The apparatus of Claim 1, wherein the treatment is at least one selected from the group consisting of thermal stimulation, mechanical stimulation, electrical stimulation, and chemical stimulation.
8. The apparatus of Claim 7, wherein the fluid line includes a delivery line that carries a fluid towards the handpiece assembly and the return line that carries the fluid away from the handpiece assembly.
9. The apparatus of Claim 8, wherein the delivery line has a passageway that is larger than a passageway of the return line.

10. The apparatus of Claim 1, wherein the handpiece assembly has a removable, disposable tip for treating skin.

11. The apparatus of Claim 10, wherein the tip includes a plurality of abrasive features.

12. The apparatus of Claim 11, wherein the plurality of skin removal features that include a spiral extending outwardly from a center region of the tip.

13. The apparatus of Claim 11, wherein the plurality of abrasive features includes diamonds, molded posts, raised sharp areas, sharp planing blades, pad, or combinations thereof.

14. The apparatus of Claim 1, wherein the plurality of fluid sources includes a plurality of bottles.

15. The apparatus of Claim 14, wherein at least one of the plurality of fluid sources contains a treatment material and at least one of the fluid sources contains an antimicrobial agent.

16. The apparatus of Claim 15, wherein the treatment material comprises at least one of a skin lightening agent, anti-aging agent, rejuvenator, and removal agent.

17. The apparatus of Claim 16, wherein the removal agent comprises salicylic acid.

18. The apparatus of Claim 14, wherein at least one of the plurality of fluid sources contains an acid peel.

19. The apparatus of Claim 1, wherein the manifold system includes a plurality of switches for terminating the flow of the treatment fluid from the plurality of bottles.

20. The apparatus of Claim 1, wherein the manifold system includes a plurality of fluid pickup tubes each pickup tube is assigned to one of each of the plurality of bottles.

21. The apparatus of Claim 1, wherein the user input device is a computer.

22. The apparatus of Claim 21, wherein the computer includes a touch screen adapted to input data into the computer.

23. The apparatus of Claim 22, wherein the computer controls a flow of fluid from the plurality of fluid sources to the handpiece assembly.

24. The apparatus of Claim 21, wherein the computer includes teaching tutorials.

25. The apparatus of Claim 21, wherein the computer includes a plurality of interchangeable program chips.

26. The apparatus of Claim 1, wherein the handpiece assembly is a light handpiece adapted to illuminate the target with light from a light source.

27. The apparatus of Claim 26, wherein the light source comprises red and infrared light emitting diodes.

28. The apparatus of Claim 27, wherein the red and infrared light emitting diodes emit a wavelength within the range of about 600 to about 1,000 nanometers.

29. The apparatus of Claim 26, wherein the light source comprises blue light emitting diodes.

30. The apparatus of Claim 29, wherein the blue light emitting diodes emit a wavelength of about 430 nanometers.

31. A tip comprising:

- a skirt portion configured to couple to a handpiece for treating a target on a patient's skin;

- a central body portion coupled to the skirt portion;

- a first passage through the central body portion configured to receive a fluid from the handpiece;

- at least one second passageway through the central body portion configured to convey the fluid back into the handpiece; and

- an inner member extending in a generally spiral fashion across at least a portion of a distal face of the central body portion, the inner member defining a channel between the first passage and the at least one second passage.

32. The tip of Claim 31, wherein the skirt portion includes a gripping surface for attaching the tip to the handpiece and removing the tip from the handpiece.

33. The tip of Claim 31, wherein the inner member extends about the surface of the central body portion about one and a half times.

34. The tip of Claim 31, wherein the inner member extends from about a center portion of the distal face of the central body portion at one end.

35. The tip of Claim 31, wherein the inner member extends from about the center portion of the distal face of the central body portion at one end to near a lateral edge of the surface of the distal face at another end.

36. The tip of Claim 31, wherein the outer member extends around the lateral edge of the central body portion.

37. The tip of Claim 31, wherein the inner member is configured to abrade the skin.

38. The tip of Claim 31, wherein the inner member is configured to ablate the skin.

39. The tip of Claim 31, wherein the at least one second passage is configured to transmit debris into the handpiece assembly.

40. The tip of Claim 31, wherein the tip is configured to apply negative pressure when the tip is in operative engagement with the target.

41. The tip of Claim 31, wherein the central body portion further includes imbedded treatment material.

42. A method of treating a target on a patient's skin, the method comprising:
providing a tip including a first aperture, at least one second aperture, at least one inner member on the surface of the tip defining at least one channel between the first aperture and the at least one second aperture, and an outer member on the surface of the tip;

engaging the target with the tip;

flowing a treatment fluid distally through the first aperture;

flowing the treatment fluid through the at least one channel; and

flowing the treatment fluid proximally through the at least one second aperture.

43. The method of Claim 42, wherein the at least one inner member defines a substantially spiral-shaped channel.

44. The method of Claim 42, wherein engaging the target includes abrading the target with the at least one inner member.

45. The method of Claim 42, wherein engaging the target includes ablating the target with the at least one inner member.

46. The method of Claim 43, wherein engaging the target includes twisting the tip about a central axis.

47. The method of Claim 46, wherein twisting the tip and flowing the treatment fluid through the channel include extracting material.

48. The method of Claim 45, wherein materials include at least one of oil, sebum, blackheads.

49. The method of Claim 42, wherein flowing the treatment fluid through the channel includes contacting the target with the treatment fluid for a detention period.

50. The method of Claim 49, wherein the treatment fluid hydrates the target.

51. The method of Claim 50, wherein twisting the tip includes removing hydrated stratum corneum from the target.

52. The method of Claim 42, further comprising flowing debris through the at least one second aperture.

53. The method of Claim 42, further comprising applying a vacuum to the at least one second aperture.

54. The method of Claim 53, wherein applying a vacuum to the at least one second aperture includes lifting the target towards the tip.

55. The method of Claim 42, further comprising applying a treatment solid coupled to the tip to the target.

56. A tip comprising:

- a skirt portion configured to couple to a handpiece for treating a target on a patient's skin;

- a central body portion coupled to the skirt portion including a structure substantially opposite the skirt portion configured to receive a pad;

- a first aperture through the skirt portion and the central body portion configured to receive a fluid from the handpiece; and

- at least one second aperture through the skirt portion and the central body portion configured to convey the fluid back into the handpiece.

57. The tip of Claim 56, further comprising a disposable pad coupled to the structure.
58. The tip of Claim 57, wherein the pad includes a plurality of abrasive features.
59. The tip of Claim 57, wherein the pad is configured to be detachable from the structure.
60. The tip of Claim 57, wherein the pad includes apertures approximately corresponding to the first aperture and the at least one second aperture.
61. The tip of Claim 57, further comprising an outer member surrounding the pad.
62. A method of treating a target region of skin, the method comprising:
providing a tip including a first aperture, at least one second aperture, and a mounting surface configured to receive a pad;
attaching a first pad to the mounting surface; and
engaging the target region with the first pad on the tip.
63. The method of Claim 62, further comprising:
flowing a treatment fluid distally through the first aperture;
flowing the treatment fluid across the first pad; and
flowing the treatment fluid proximally through the at least one second aperture.
64. The method of Claim 62, further comprising:
removing the first pad from the mounting surface;
attaching a second pad to the structure; and
engaging the target with the tip including the second pad.
65. The method of Claim 62, wherein engaging the target region with the tip includes abrading the target region with the first pad.
66. The method of Claim 63, wherein the tip further includes an outer member substantially surrounding the mounting surface and configured to contain the treatment fluid within the tip.
67. The method of Claim 63, wherein flowing the treatment fluid through the channel includes contacting the treatment fluid with the target region for a detention period.
68. The method of Claim 63, wherein the treatment fluid hydrates the skin.

69. The method of Claim 62, further comprising flowing debris through the at least one second aperture.

70. The method of Claim 62, further comprising applying a vacuum to the at least one second aperture.

71. The method of Claim 70, wherein applying a vacuum to the at least one second aperture lifts the target region towards the tip.

72. The method of Claim 62, further comprising applying a treatment solid coupled to the tip to the target.

73. A method of treating a target on a patient's skin, the method comprising:
engaging a dry tip with the patient's skin such that an effective amount of skin is removed by the tip; and

after removing an effective amount of skin with the dry tip, engaging a wet tip with the patient's skin such that an effective amount of skin is removed by the wet tip.

74. The method of Claim 73, further comprising delivering an acid out of the wet tip to facilitate skin removal.

75. The method of Claim 73, wherein the wet tip includes a first aperture, at least one second aperture, at least one inner member on the surface of the tip defining at least one channel between the first aperture and the at least one second aperture, and an outer member on the surface of the tip.

76. The method of Claim 75, further comprising flowing a treatment fluid outwardly along the at least one channel.

77. The method of Claim 75, further comprising flowing a treatment fluid inwardly along the at least one channel.

78. A method of treating a target on a patient's skin, the method comprising:
engaging a first skin treatment tip with the target region of the patient's skin;
apply a first material out of the first skin treatment tip to a target region of the patient's skin; and

engaging a second skin treatment tip with the target region while the first material effectively facilitates exfoliation of the target region.

79. The method of Claim 78, wherein the first material comprises an acid, hydrator, and combination thereof.

80. The method of Claim 78, wherein the first skin treatment tip is configured to remove skin at a different rate than the second skin treatment tip.

81. The method of Claim 78, wherein the first skin treatment tip is configured to remove skin at a higher rate than the second skin treatment tip.

82. The method of Claim 78, further comprising delivering material out of the second treatment tip to the target region of the patient's skin.

83. A manifold system comprising:

- a body portion configured to releasably receive at least two bottles and configured to be coupled to a console, the console including a handpiece for treating skin;

- at least one elongate member in communication with a pump and configured to extract a fluid from one of the at least two bottles; and

- at least one switch configured to permit or inhibit a flow of the fluid from one of the at least two bottles through the pump.

84. The manifold system of Claim 83, wherein the elongate member includes a lancing tip for breaking a seal of one or the bottles.

85. The manifold system of Claim 83, wherein the body portion is configured to allow placement of the manifold system on more than one console without removing the at least two bottles.

86. The manifold system of Claim 83, further comprising quick-release locks corresponding to each of the at least two bottles and configured to capture and release one of the at least two bottles.

87. The manifold system of Claim 86, wherein the quick-release locks are configured to fasten a bottle to the manifold system upon reception of the bottle by the body portion and to release the bottle from the manifold system upon activation of a release mechanism.

APPARATUS AND METHODS FOR TREATING THE SKIN

Abstract of the Disclosure

[0151] An apparatus for treating skin has a console with a user input device and a handpiece assembly. The handpiece assembly is configured to treat skin. A fluid line provides fluid communication between the console and the handpiece assembly. A manifold system is coupled to the console and controlled by the user input device. The manifold system is configured to hold releasably a plurality of fluid sources and deliver fluid from at least one of the plurality of fluid sources to the handpiece assembly.

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APPARATUS AND METHODS FOR TREATING THE SKIN

Ignon, et al.

Appl. No.: Unknown Atty Docket: EDGE.005PR2

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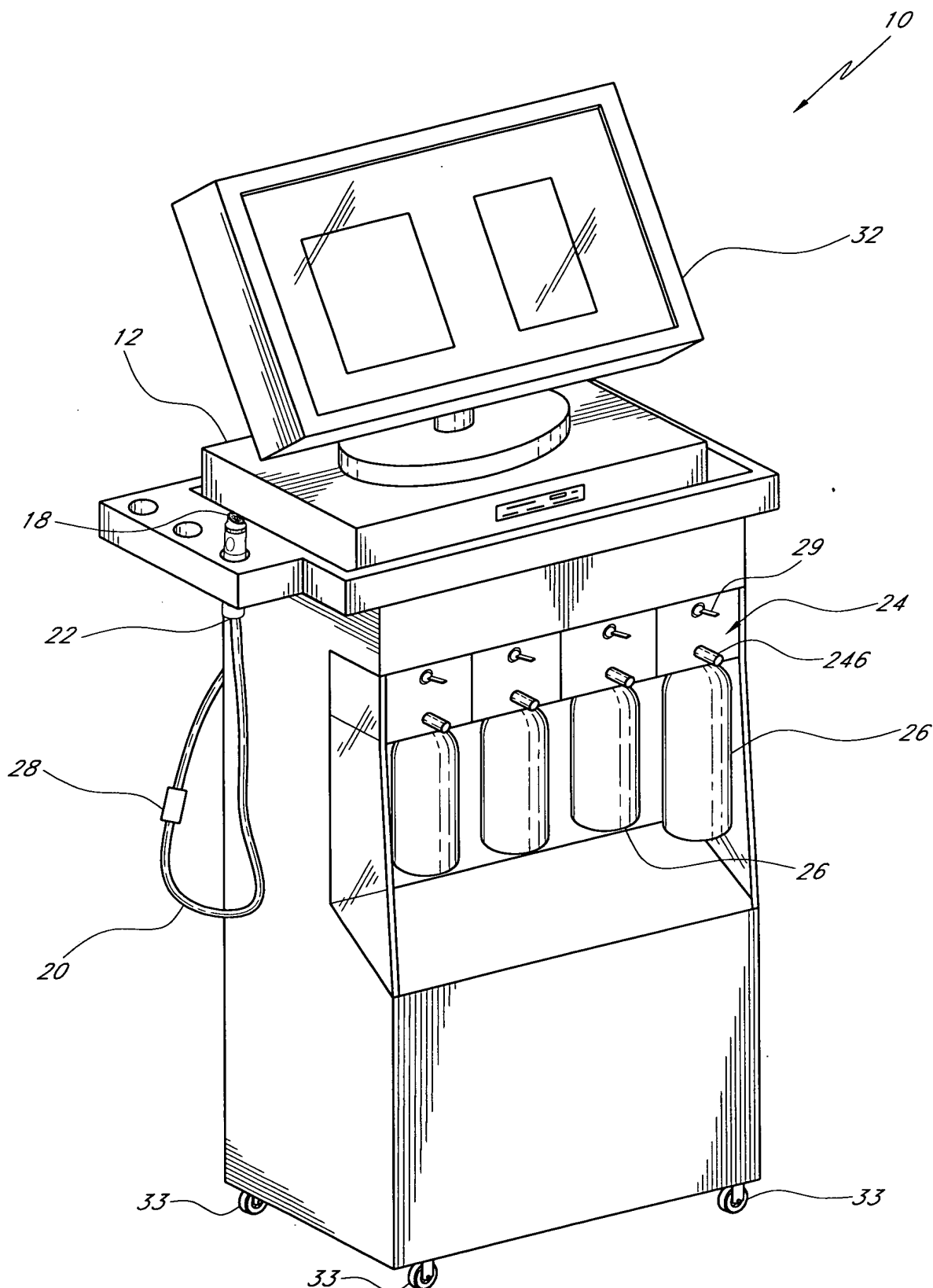
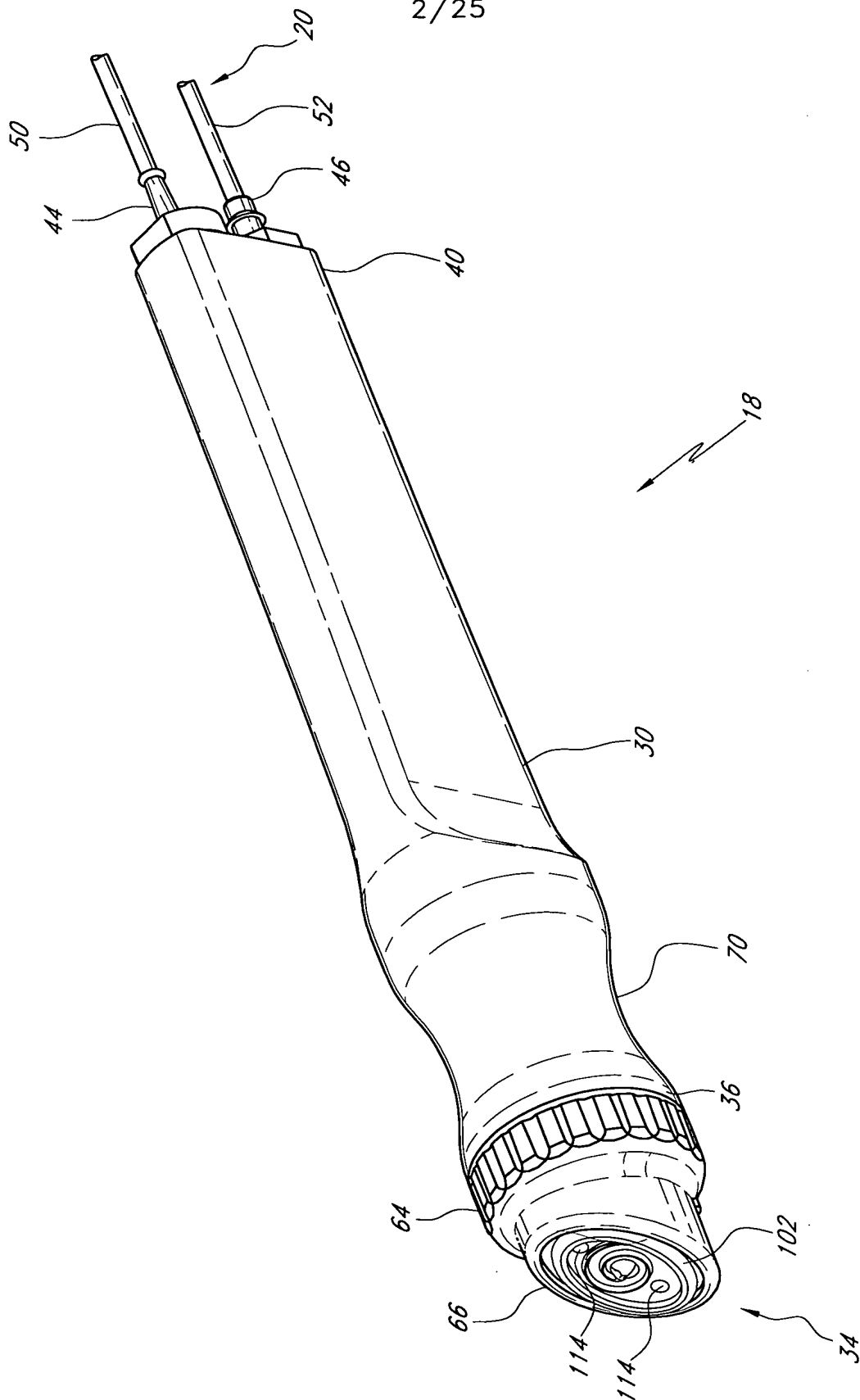


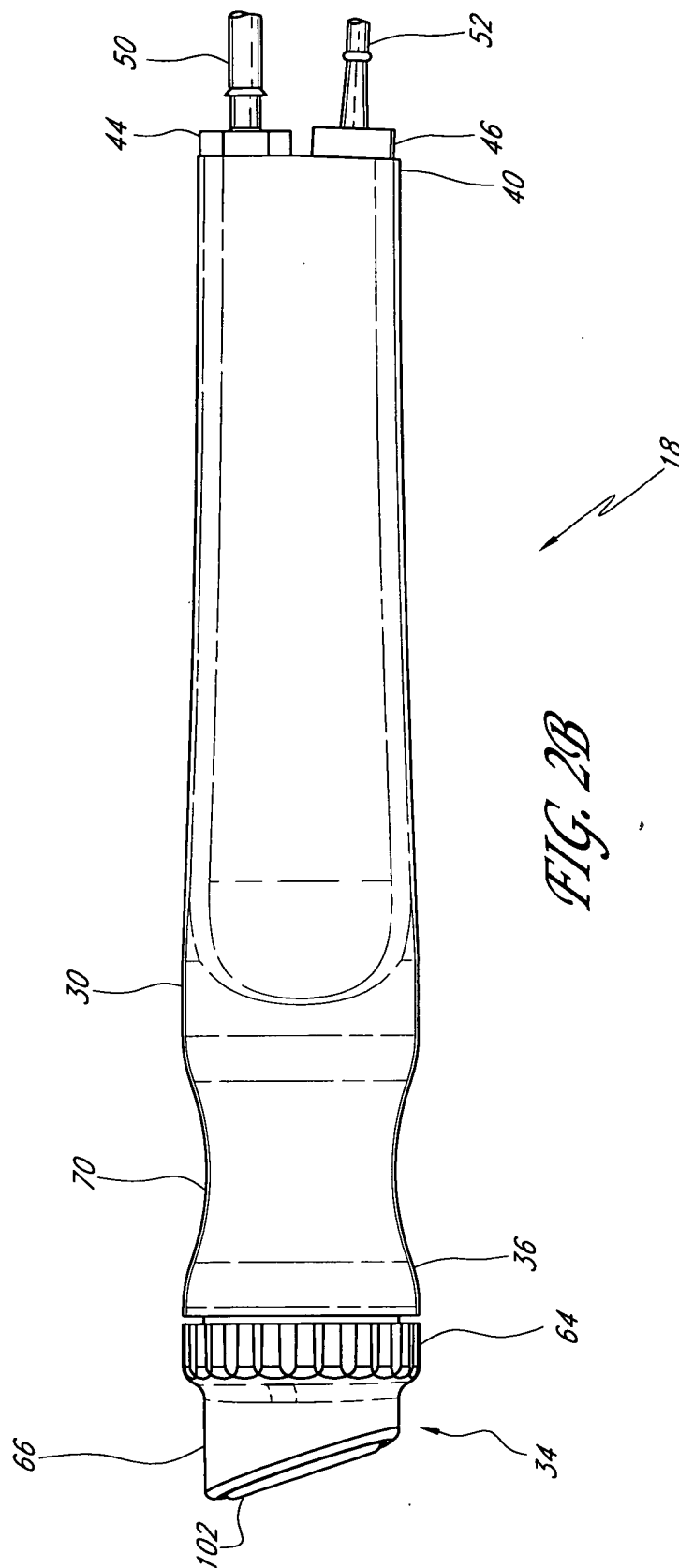
FIG. 1

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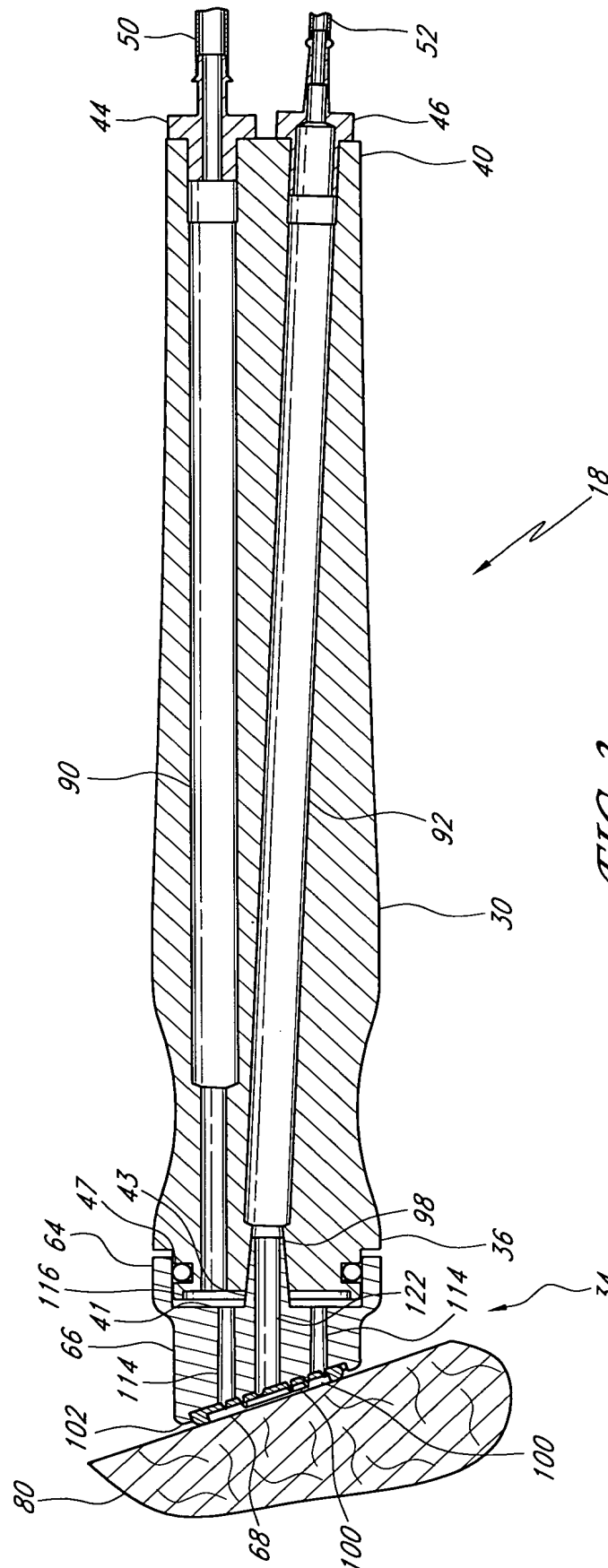
FIG. 2A



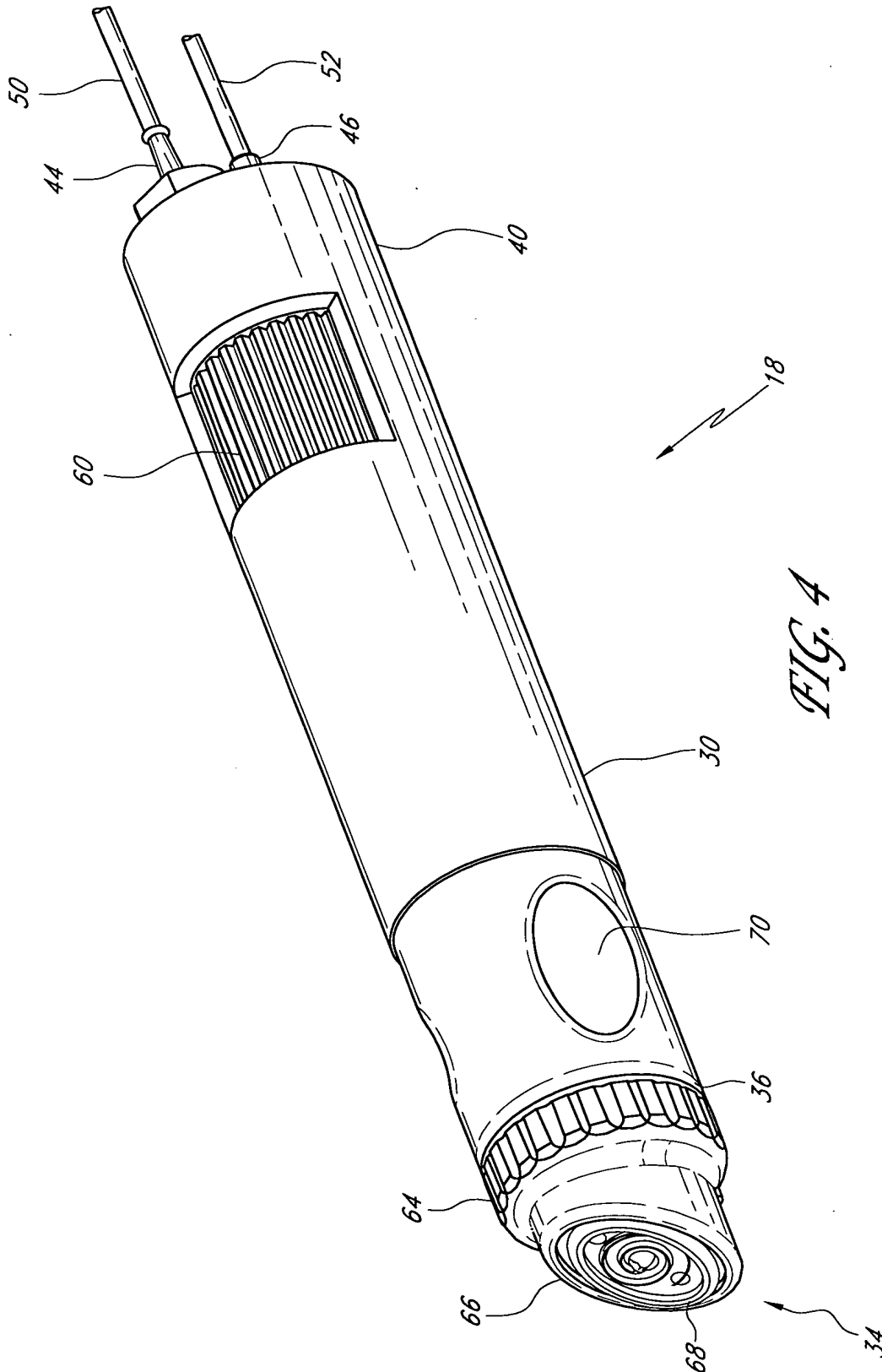
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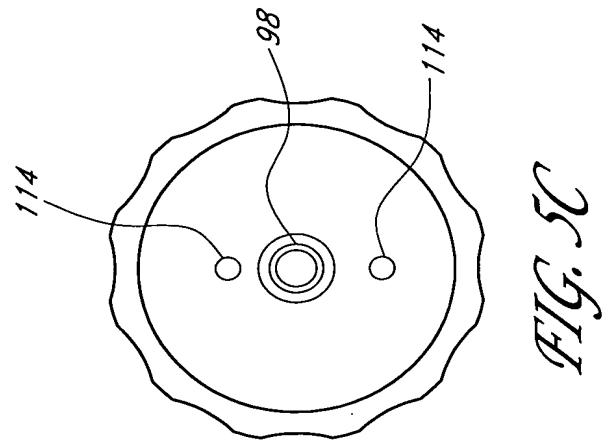
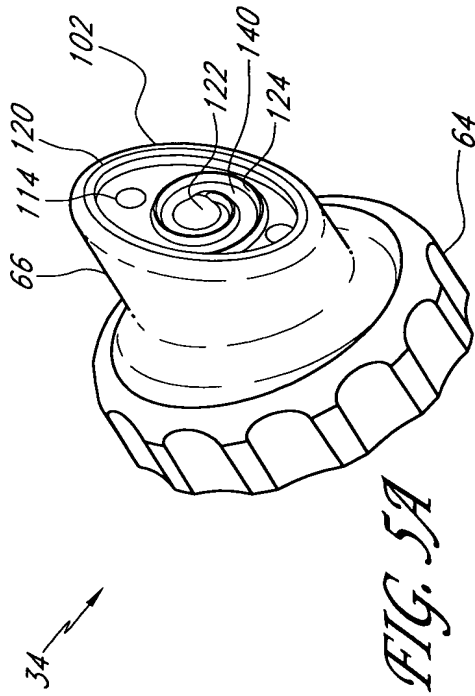
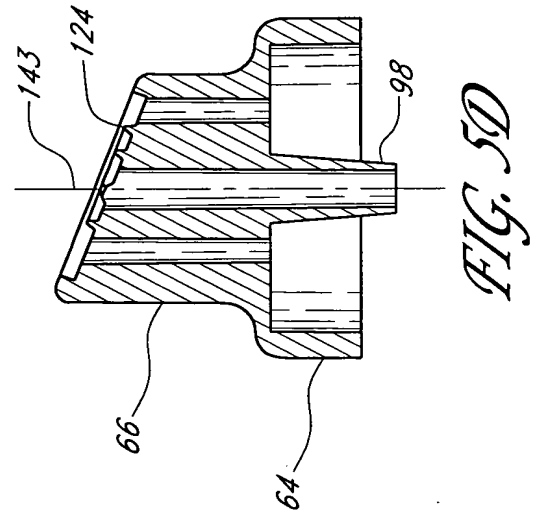
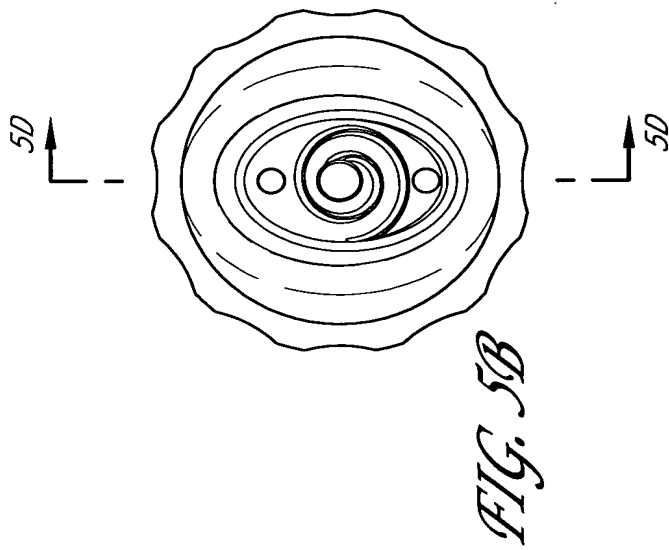
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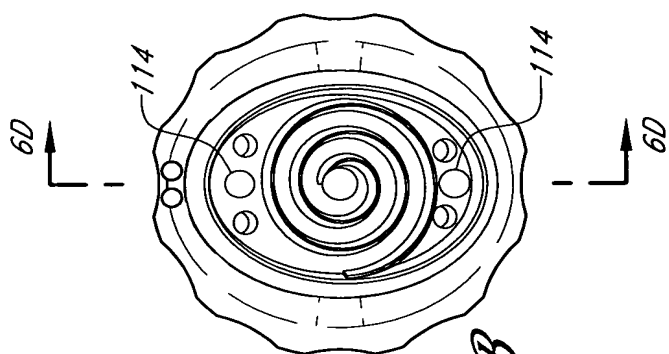


FIG. 6B

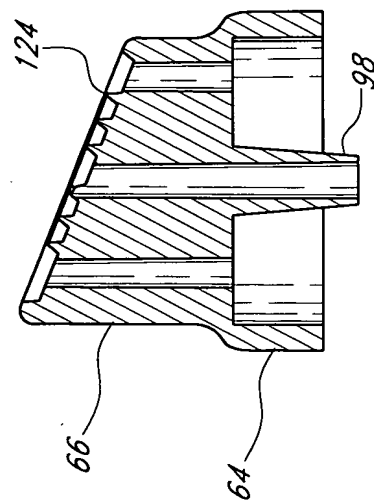


FIG. 6D

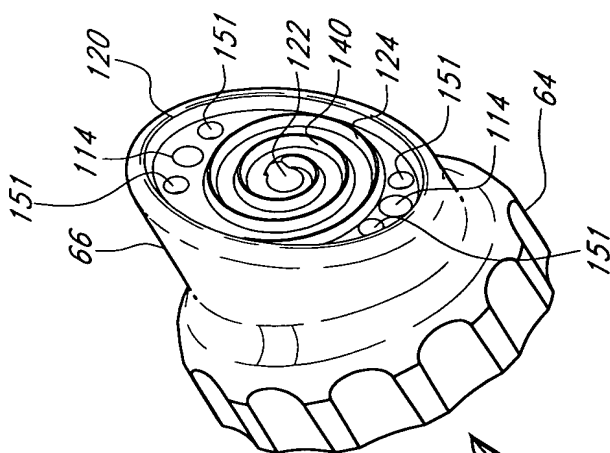


FIG. 6A

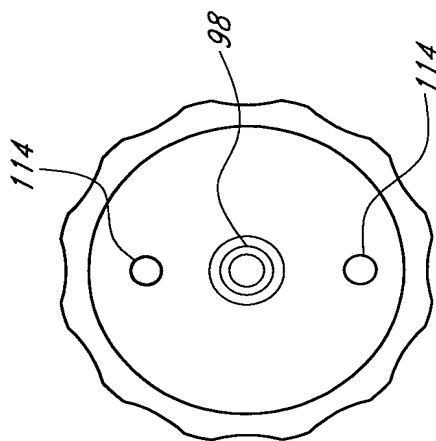


FIG. 6C

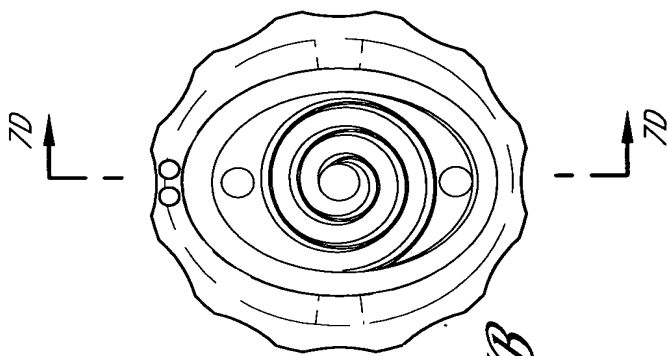


FIG. 7B

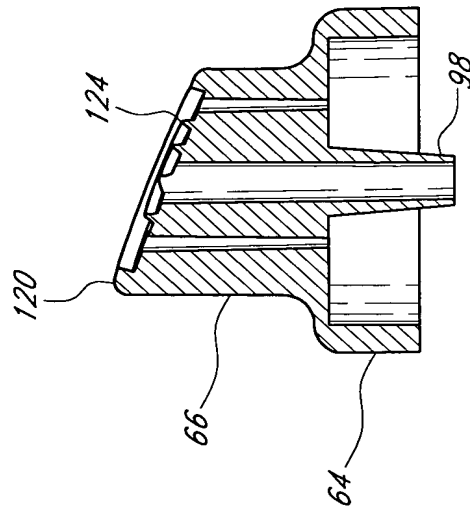


FIG. 7D

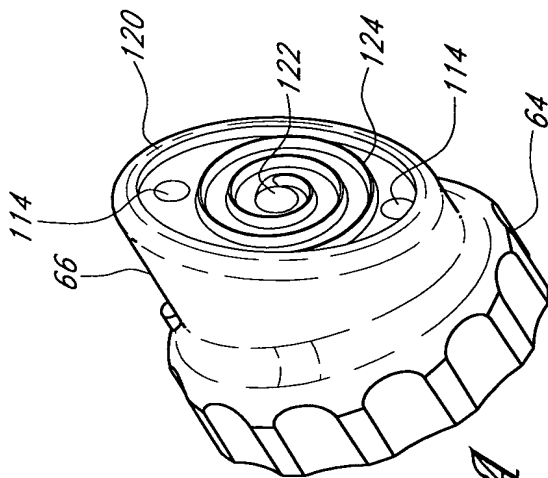


FIG. 7A

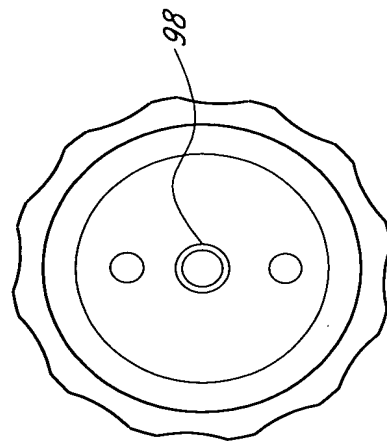


FIG. 7C

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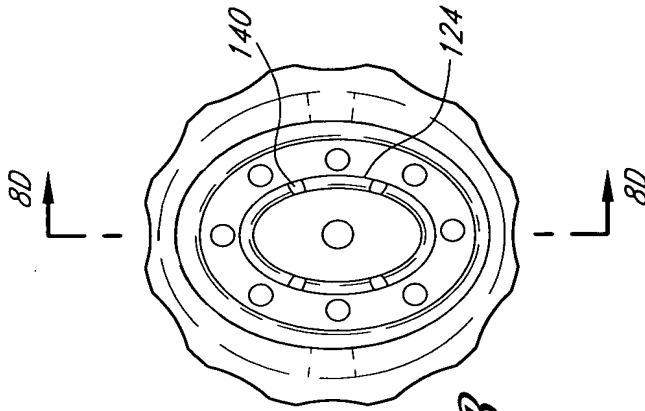


FIG. 8B

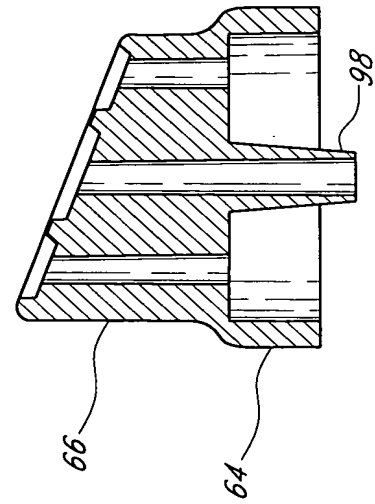


FIG. 8D

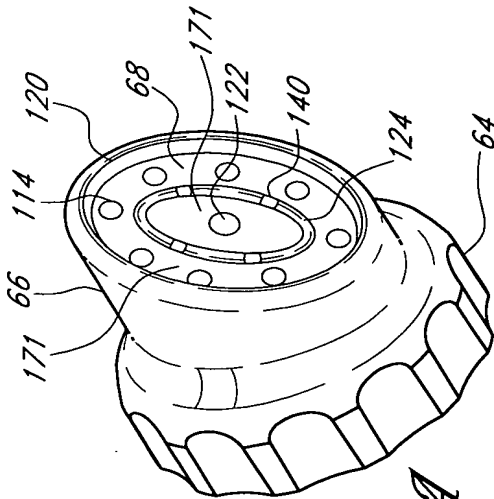


FIG. 8A

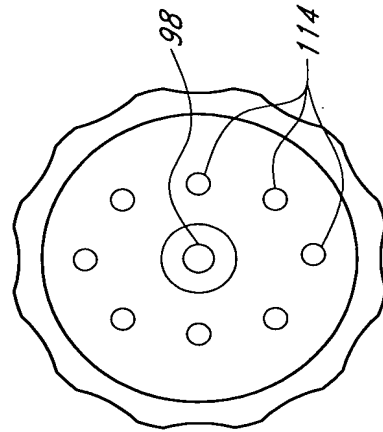
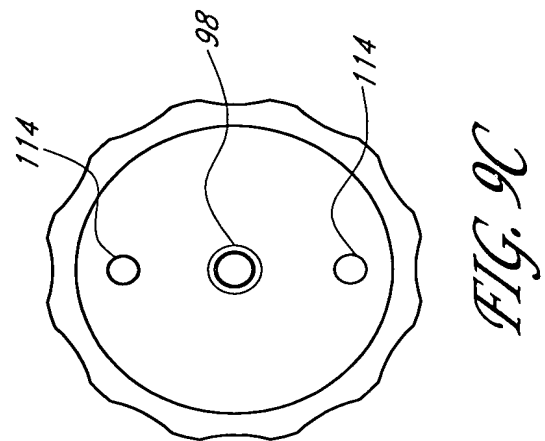
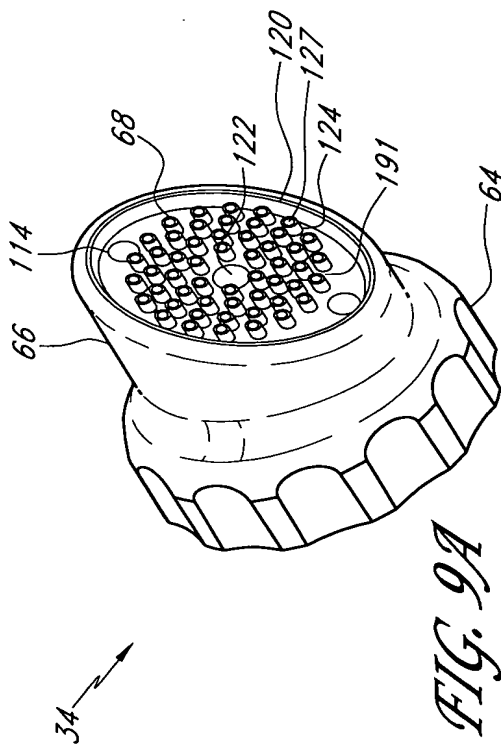
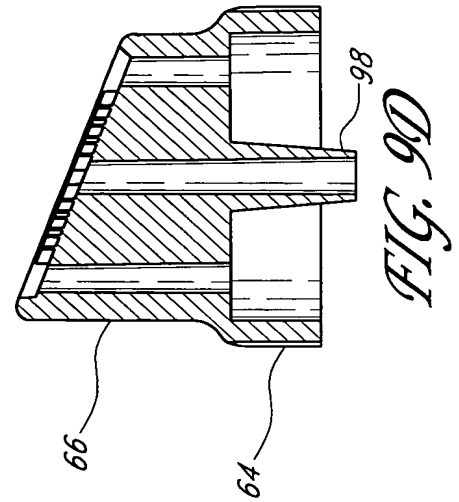
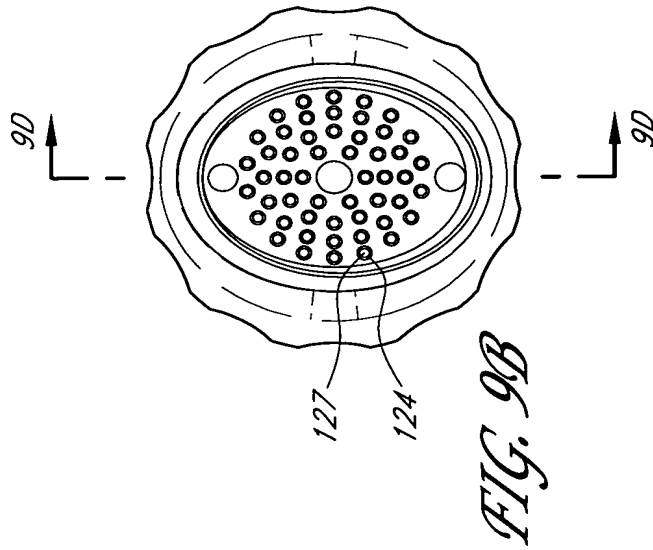


FIG. 8C

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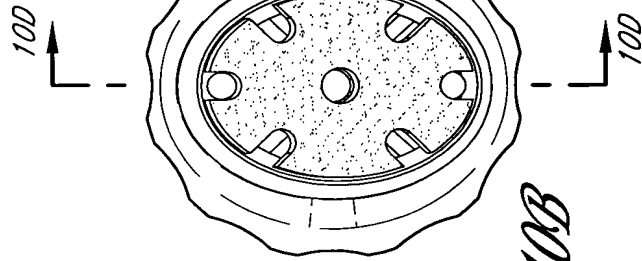


FIG. 10B

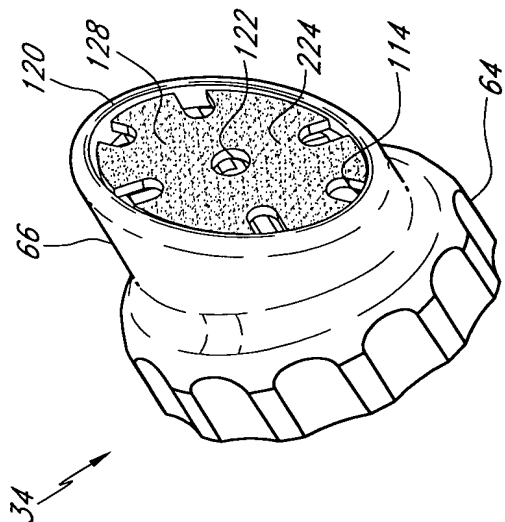


FIG. 10A

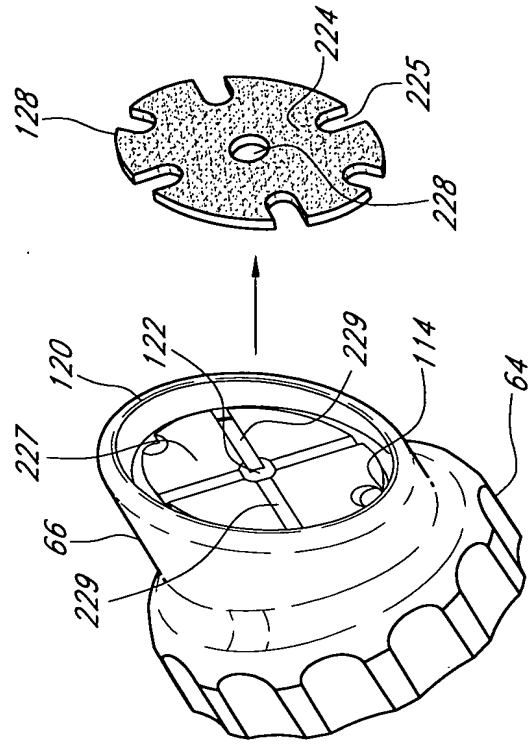


FIG. 10E

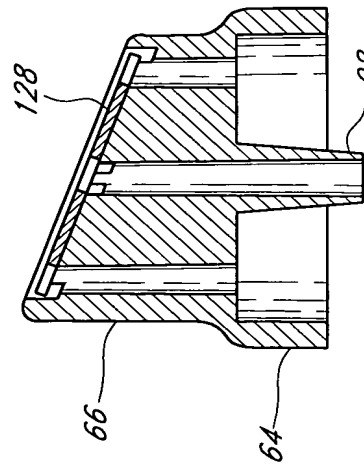


FIG. 10D

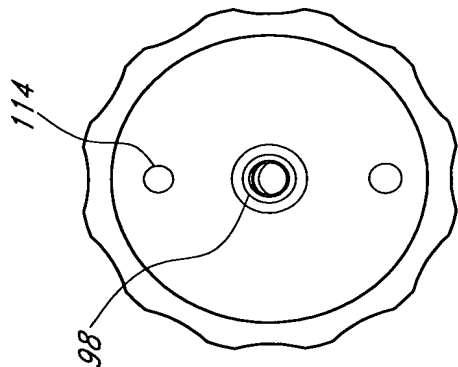


FIG. 10C

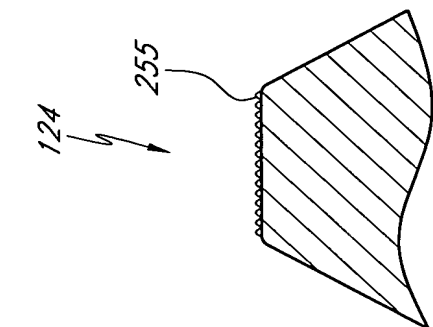


FIG. 11A

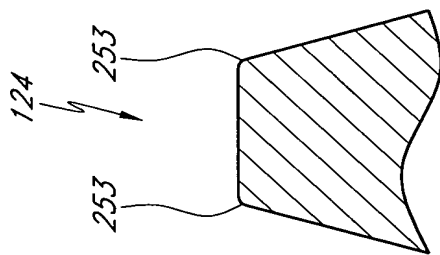


FIG. 11B

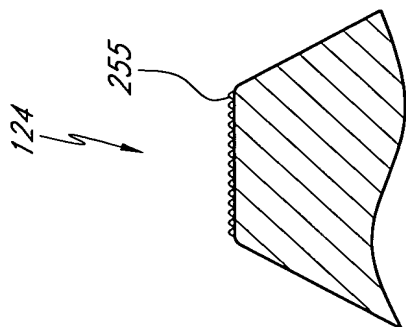


FIG. 11C

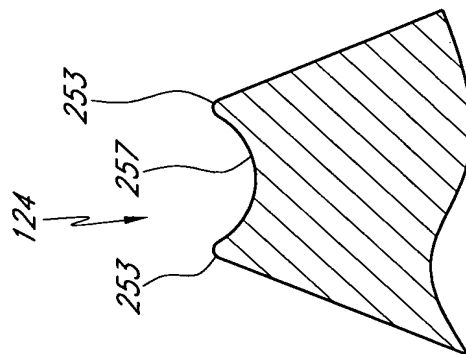


FIG. 11D

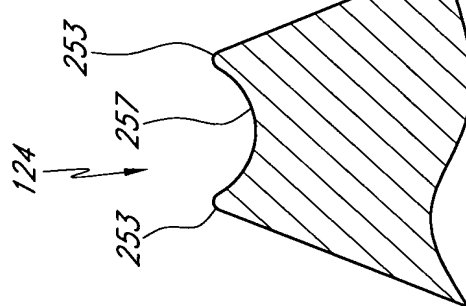


FIG. 11E

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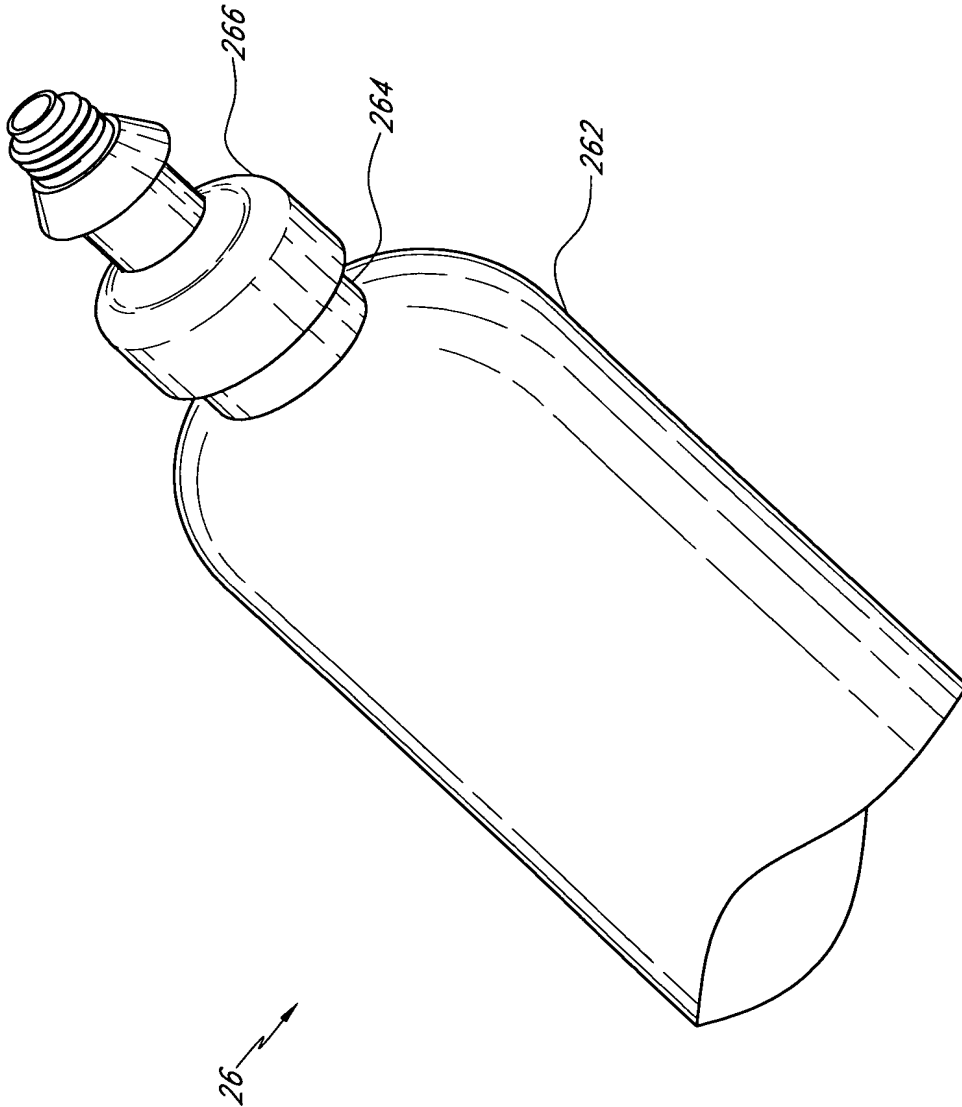


FIG. 12

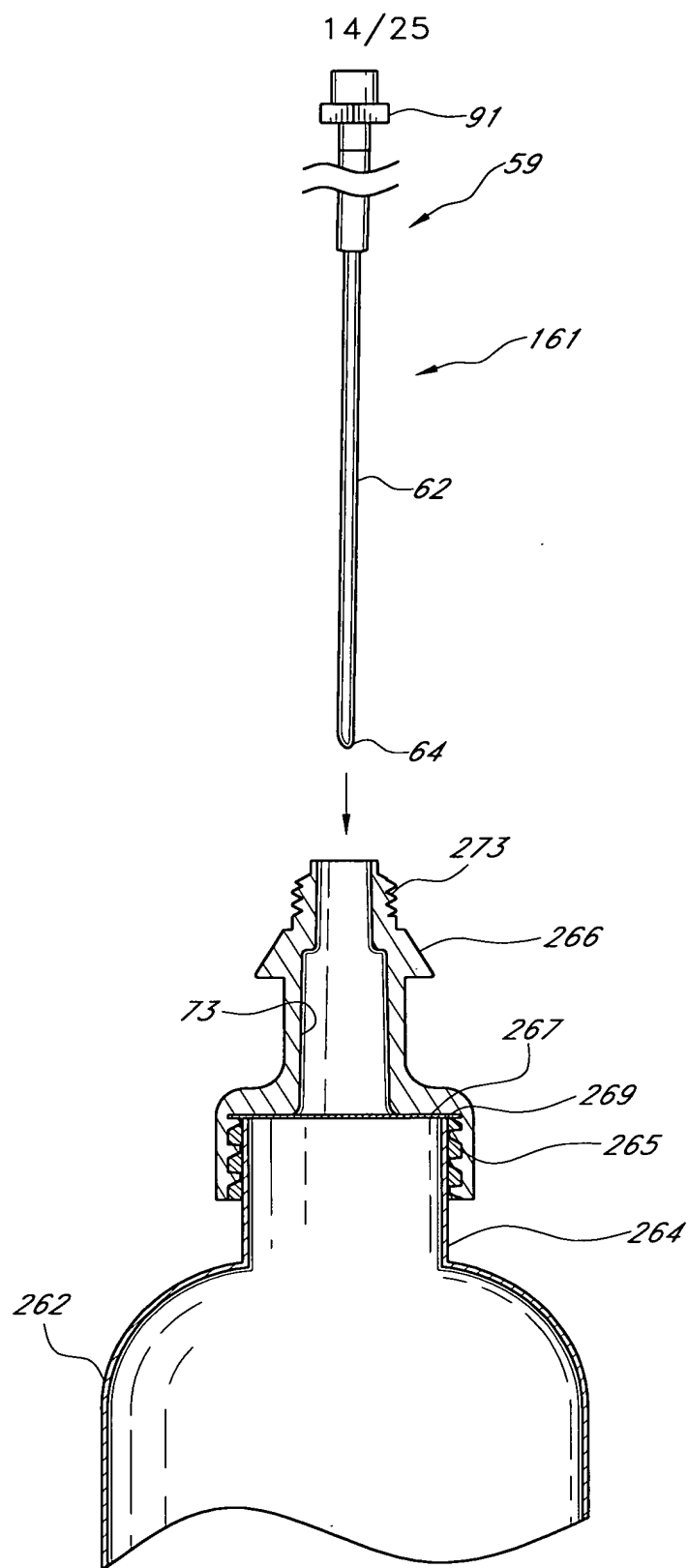


FIG. 13A

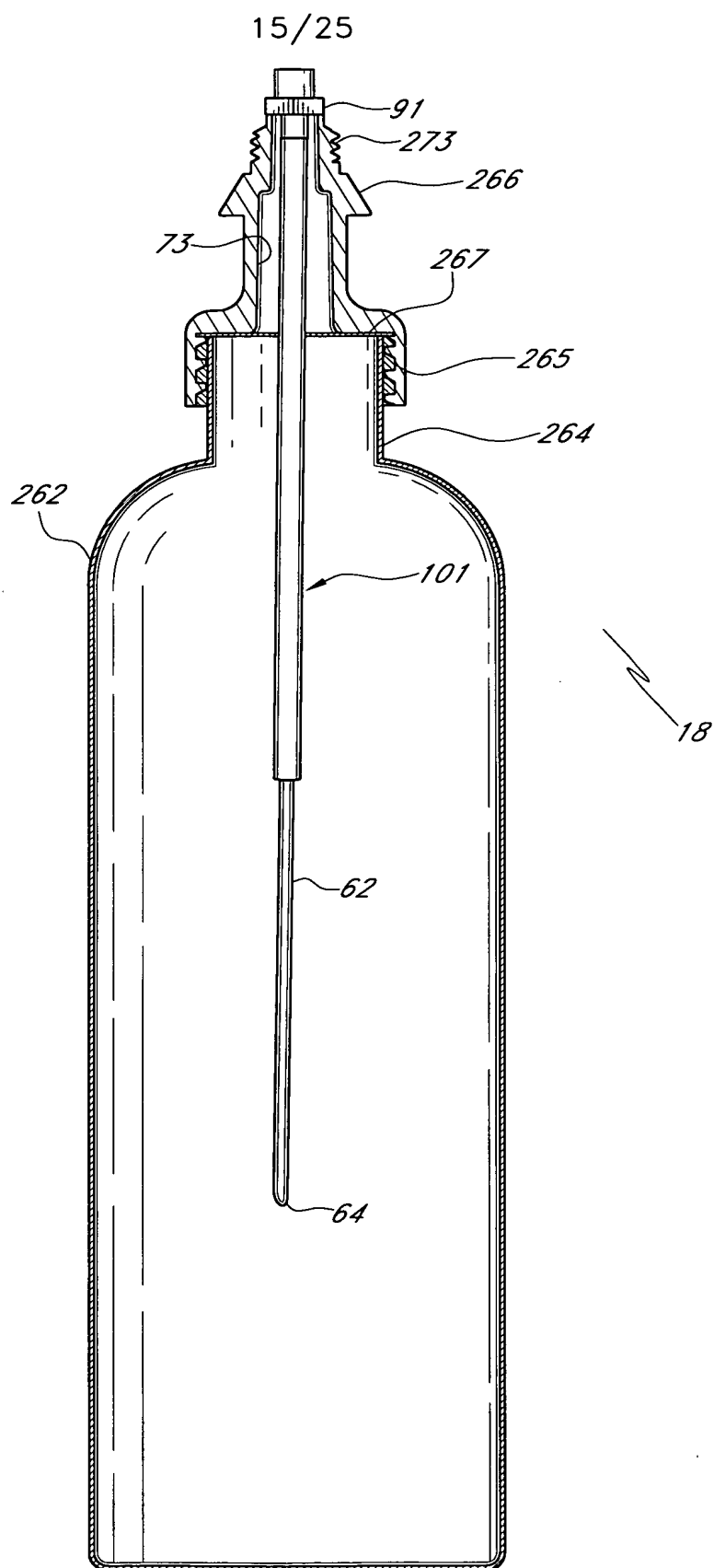


FIG. 13B

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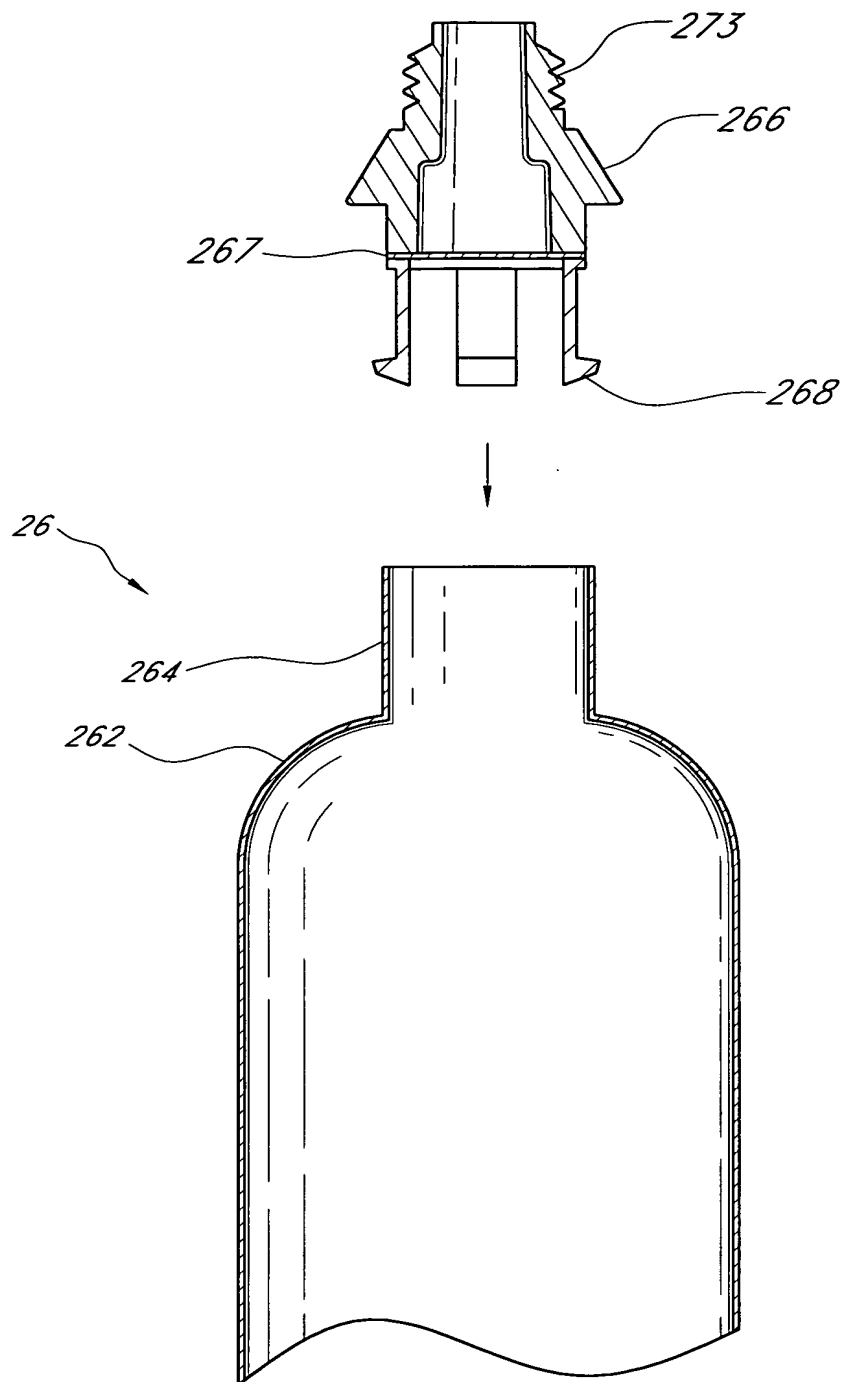


FIG. 14A

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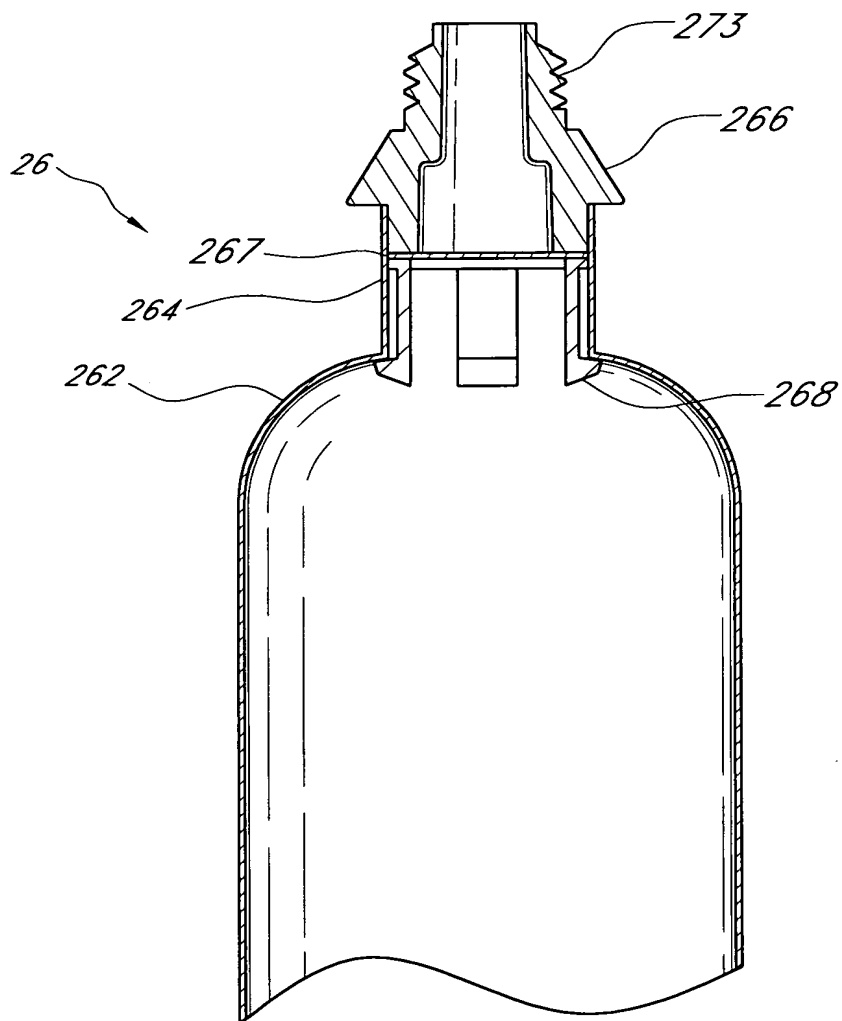
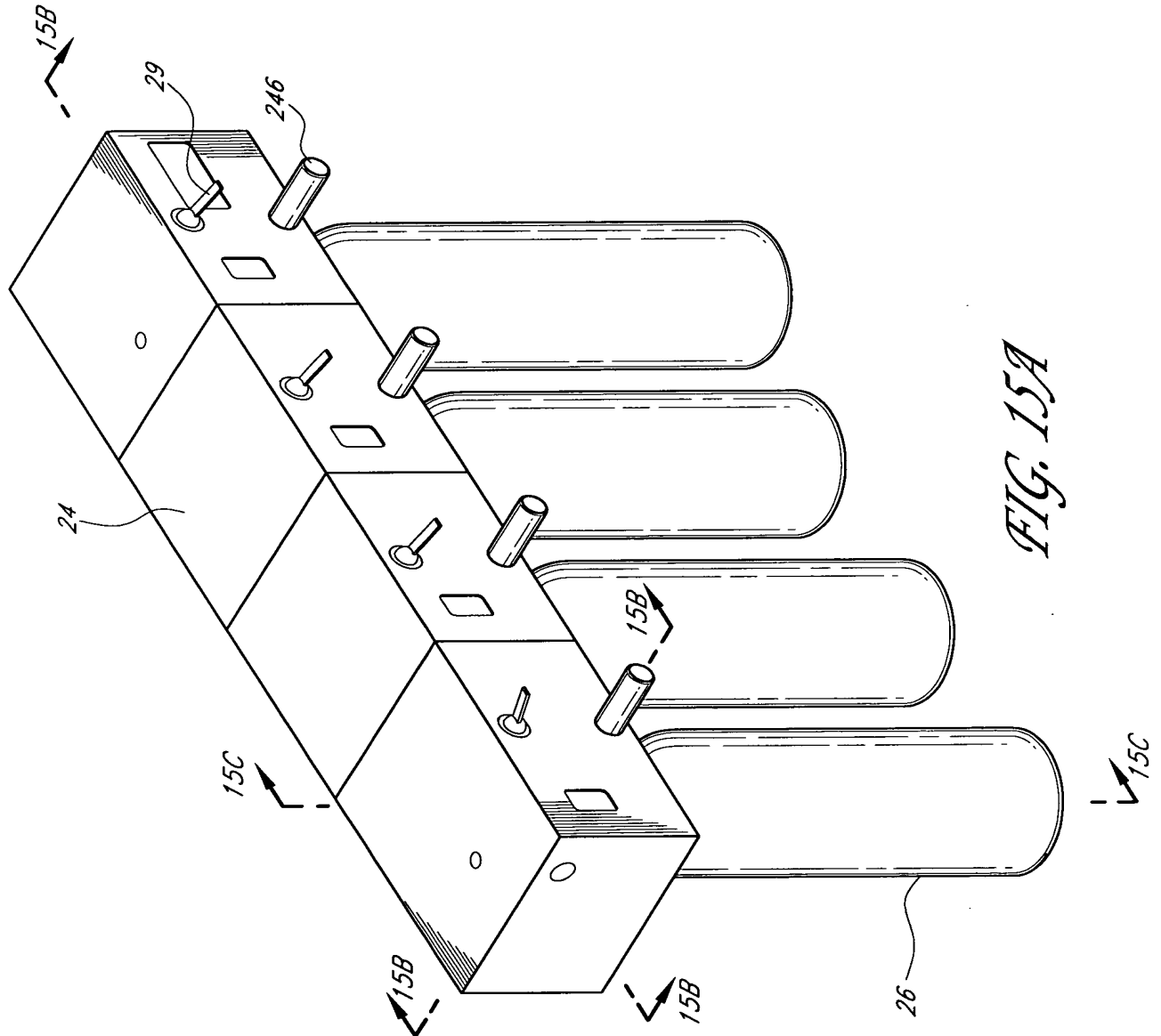


FIG. 14B

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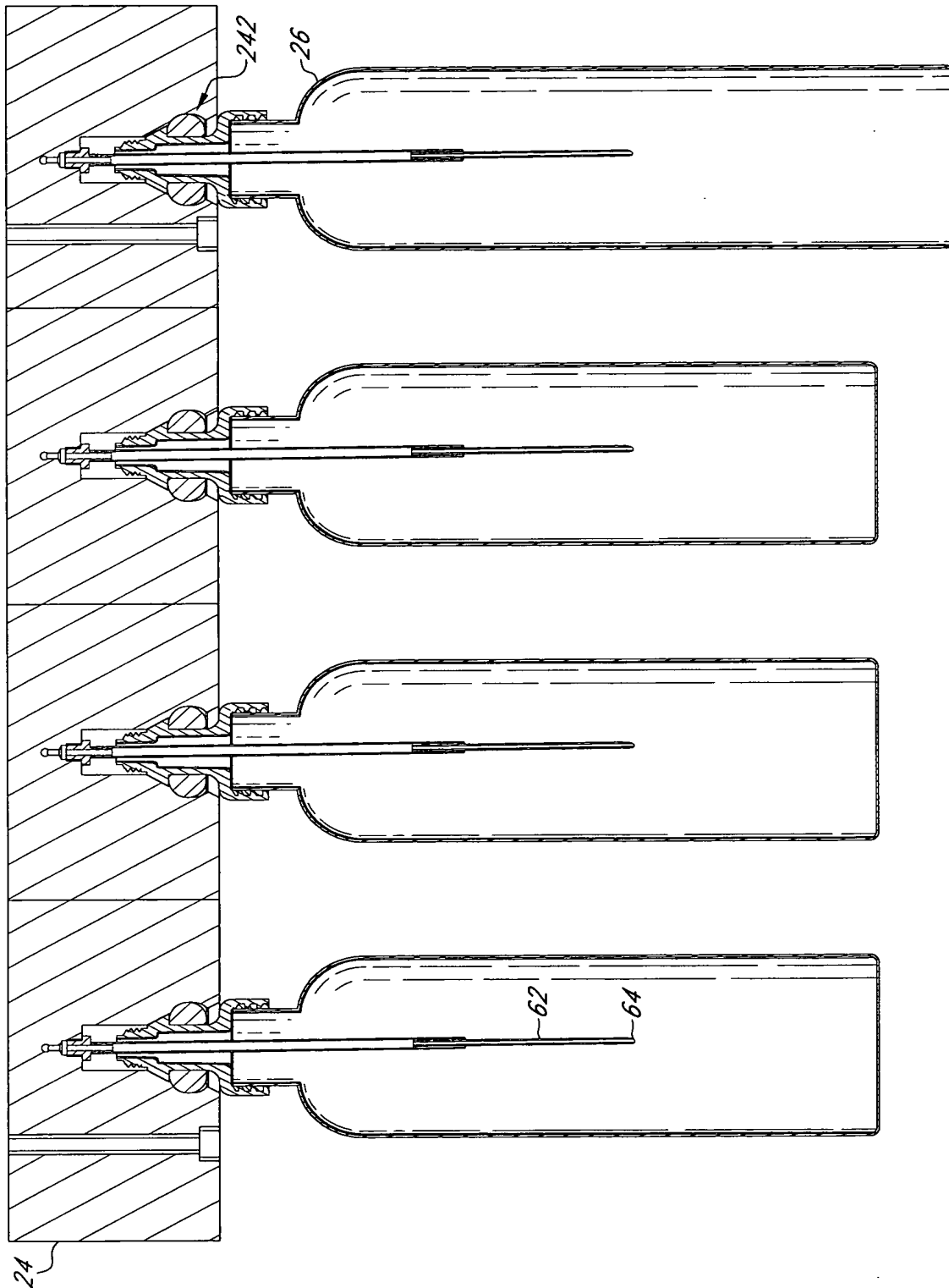


FIG. 15B

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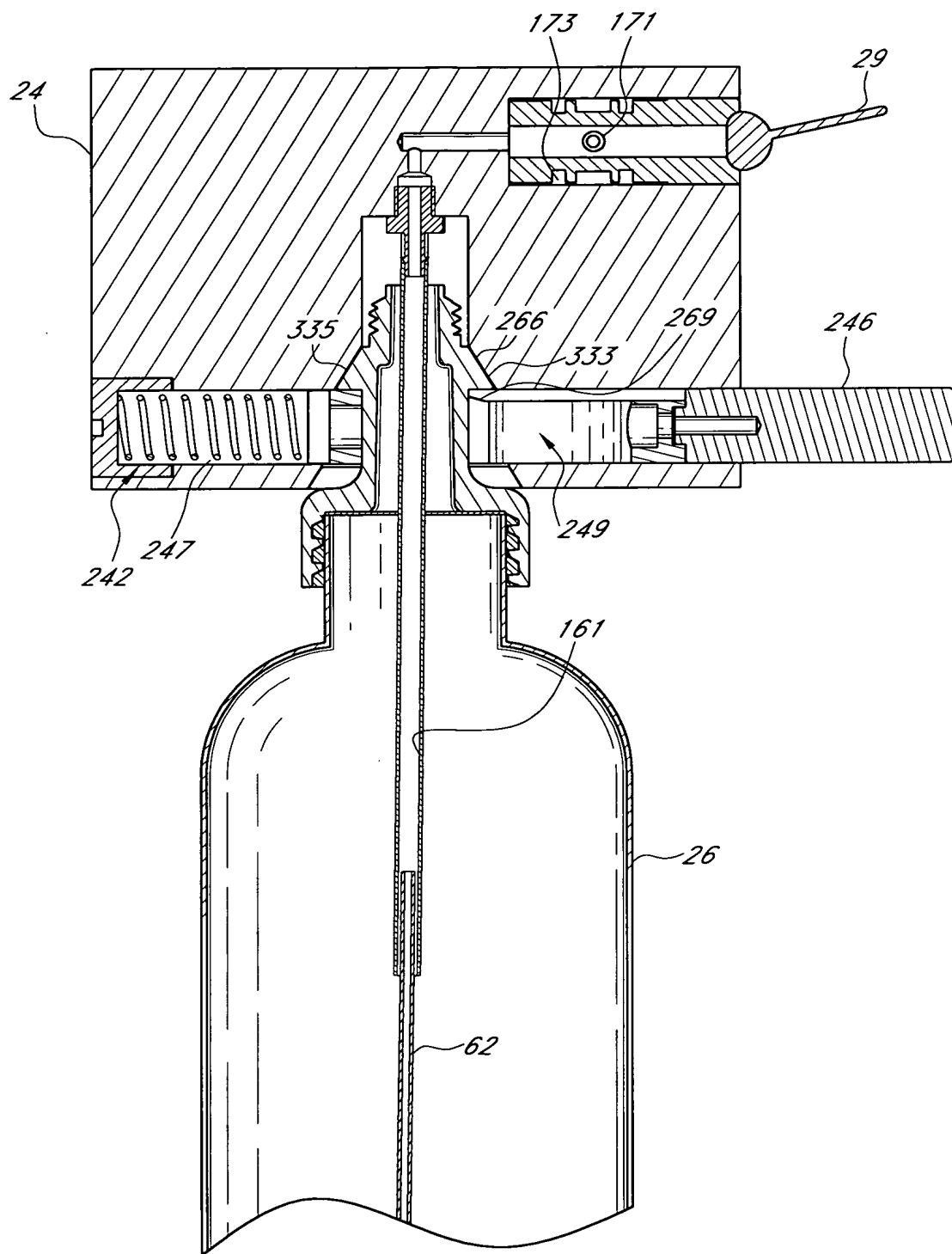


FIG. 15C

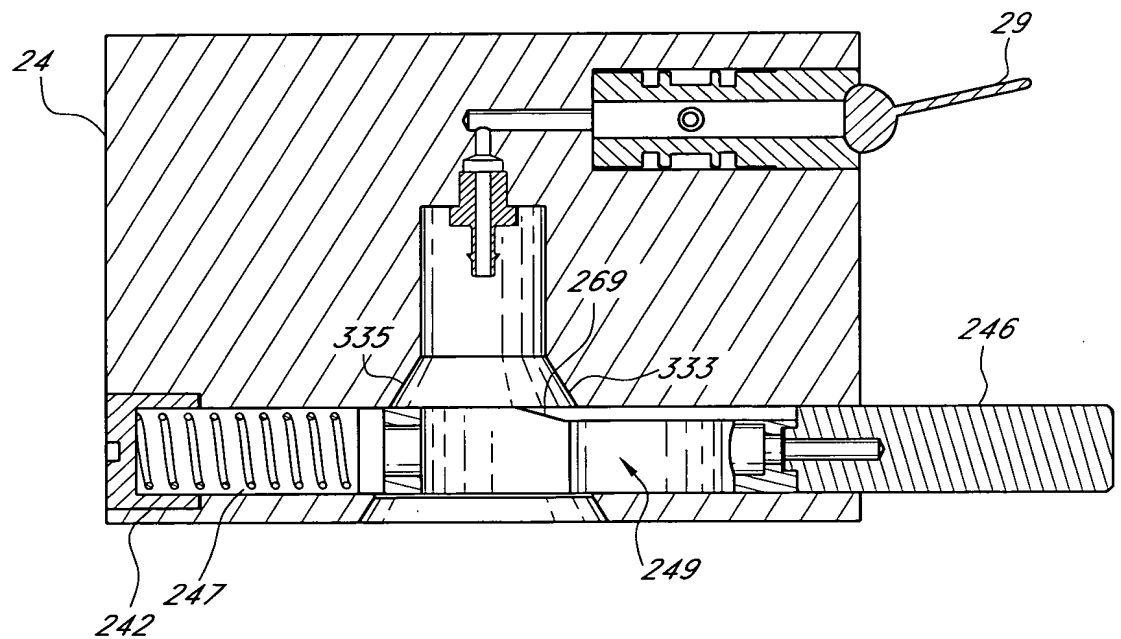


FIG. 15D

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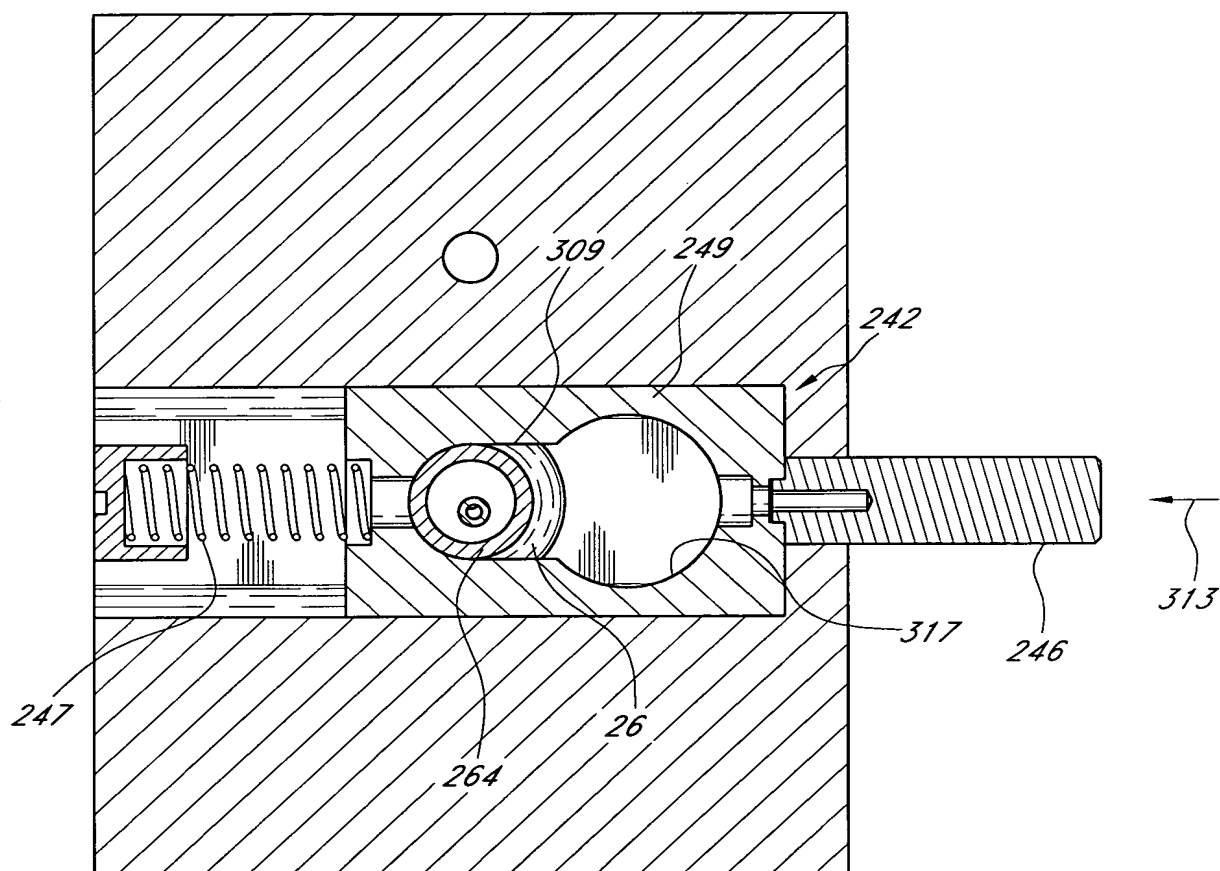


FIG. 15E

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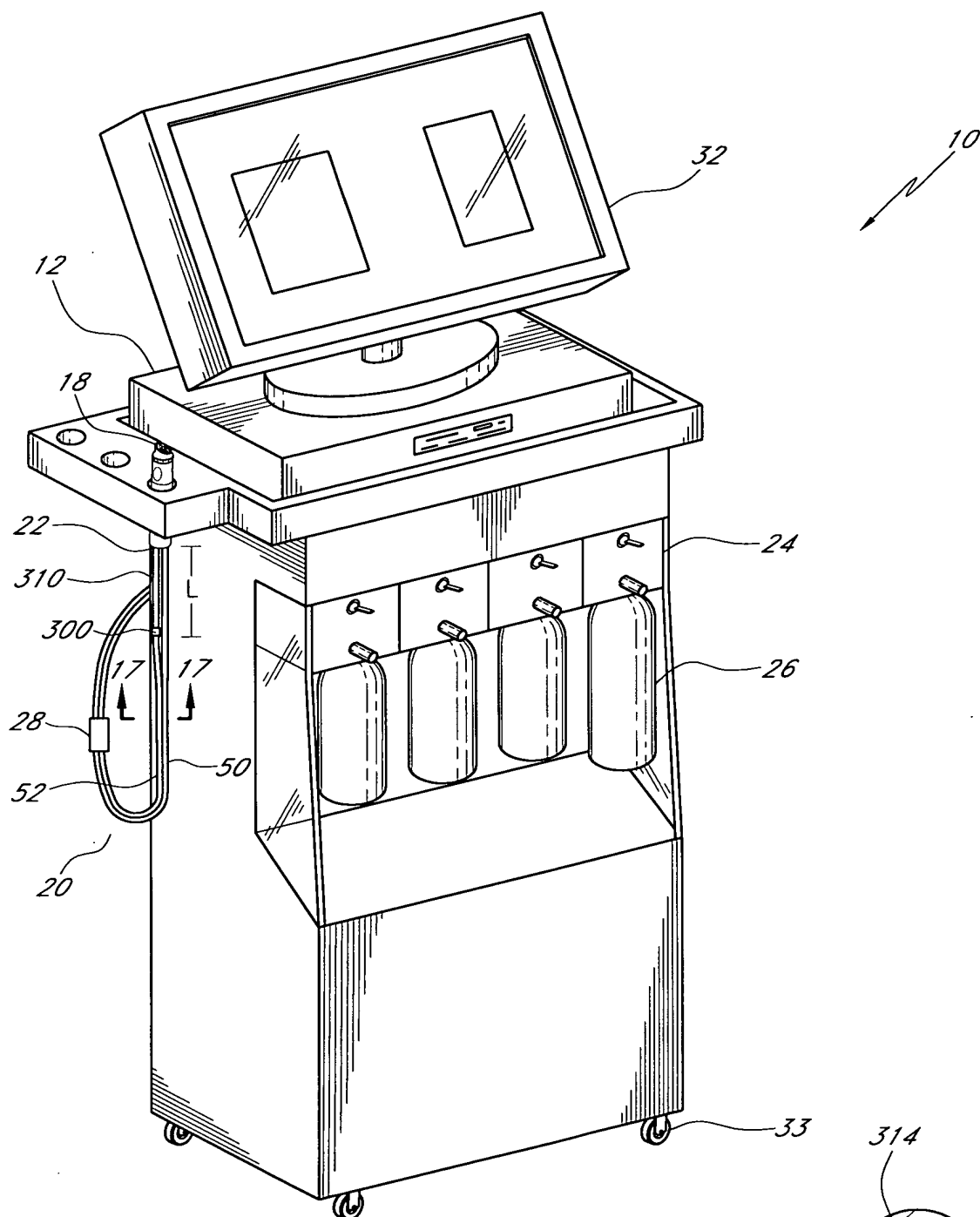


FIG. 16

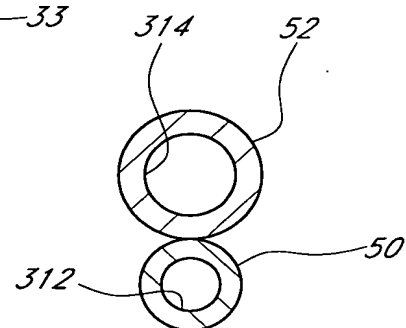
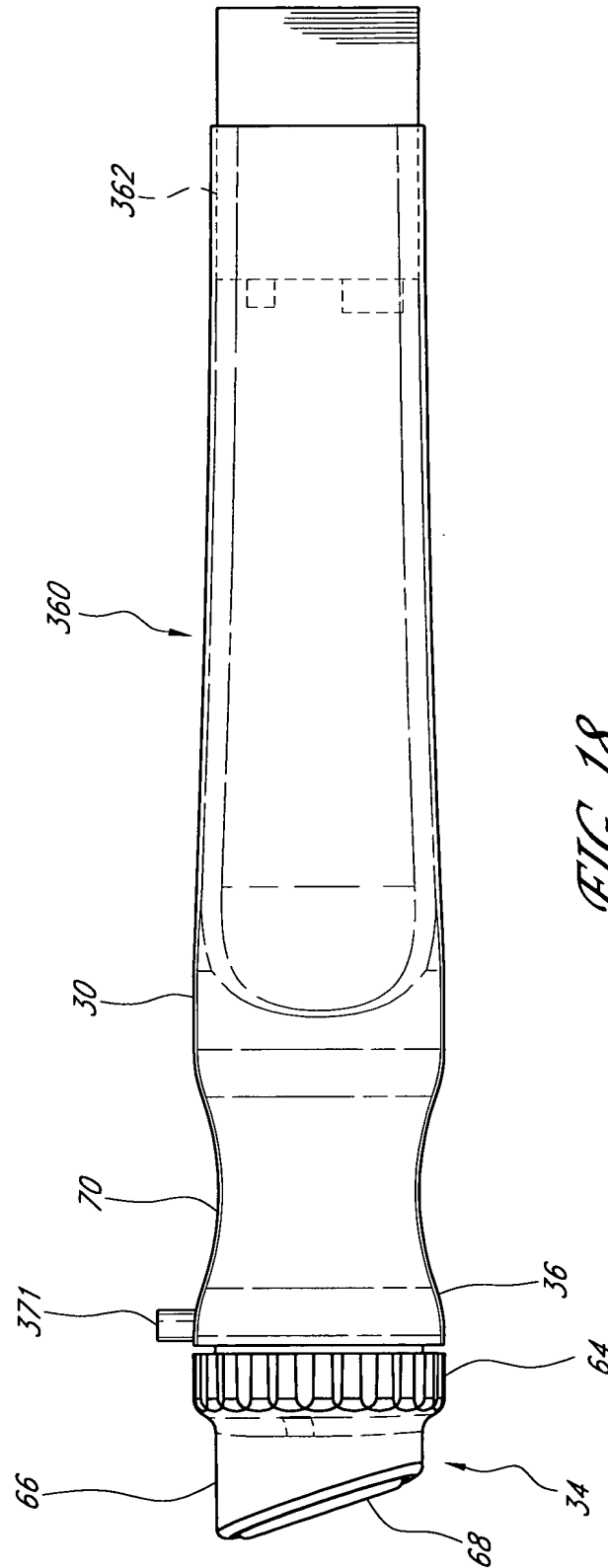


FIG. 17

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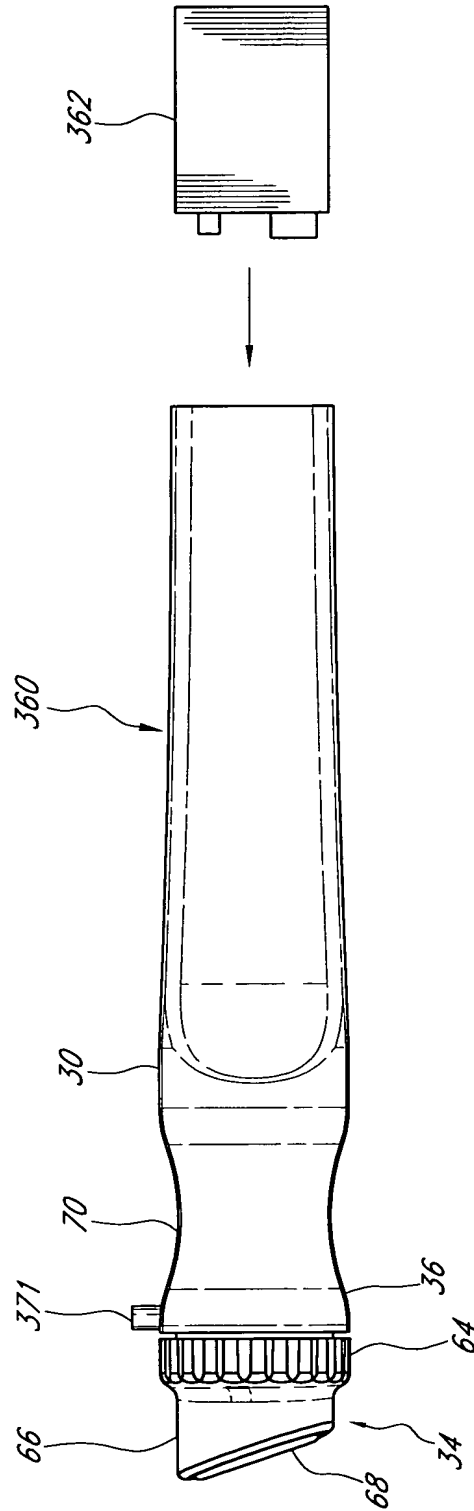


FIG. 19

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