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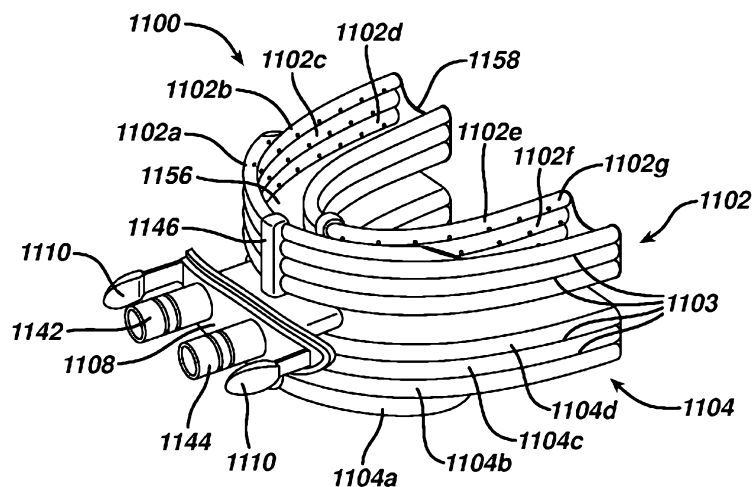
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[Continued on next page]

(54) Title: ORAL CARE DEVICE

FIG. 17



(57) Abstract: A device for directing a liquid onto a plurality of surfaces of the oral cavity, the device including a chamber for maintaining the liquid proximate the surfaces, where the chamber is defined by front, rear and base inner walls of the device and the front and rear inner walls each include a plurality of openings, the devices further including a first manifold and a second manifold, a first port and a second port; and means for providing an effective seal of the device within the oral cavity.



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ORAL CARE DEVICE

FIELD OF THE INVENTION

[0001] The present invention relates to oral care devices suitable for in-home use to provide a beneficial effect to the oral cavity of a mammal.

BACKGROUND OF THE INVENTION

[0002] In addition to regular professional dental checkups, daily oral hygiene is generally recognized as an effective preventative measure against the onset, development, and/or exacerbation of periodontal disease, gingivitis and/or tooth decay. Unfortunately, however, even the most meticulous individuals dedicated to thorough brushing and flossing practices often fail to reach, loosen and remove deep-gum and/or deep inter-dental food particulate, plaque or biofilm. Most individuals have professional dental cleanings biannually to remove tarter deposits.

[0003] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

[0004] For many years products have been devised to facilitate the simple home cleaning of teeth, although as yet a single device which is simple to use and cleans all surfaces of a tooth and/or the gingival or sub-gingival areas simultaneously is not available. The conventional toothbrush is widely utilized, although it requires a significant input of energy to be effective and, furthermore, a conventional toothbrush cannot adequately clean the inter-proximal areas of the teeth. Cleaning of the areas between teeth currently requires the use of floss, pick, or some such other additional device apart from a toothbrush.

[0005] Electric toothbrushes have achieved significant popularity and, although these reduce the energy input required to utilize a toothbrush, they are still inadequate to ensure proper inter-proximal tooth cleaning. Oral irrigators are known to clean the inter-proximal area between teeth. However, such devices have a single jet which must be directed at the precise inter-proximal area involved in order to remove debris. These water pump type cleaners are therefore typically only of significant value in connection with teeth having braces thereupon which often trap large particles of food. It will be appreciated that if both debris and plaque are

to be removed from teeth, at present a combination of a number of devices must be used, which is extremely time consuming and inconvenient.

[0006] In addition, in order for such practices and devices to be effective, a high level of consumer compliance with techniques and/or instructions is required. The user-to-user variation in time, cleaning/treating formula, technique, etc., will affect the cleaning of the teeth.

[0007] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

SUMMARY OF THE INVENTION

[0008] Accordingly, the invention provides a device for directing a liquid onto a plurality of surfaces of an oral cavity of a mammal, said device comprising,

a chamber for maintaining said liquid proximate said plurality of surfaces, said chamber defined by front and rear inner walls and a base inner wall of said device, said base wall extending between said front and rear inner walls, but not comprising a rear gum-sealing membrane defining said chamber, said front and rear inner walls comprising a plurality of openings,

a first manifold for containing a first portion of said liquid and providing said first portion to said chamber through said openings of said front inner wall,

a second manifold for containing a second portion of said liquid and providing said second portion to said chamber through said openings of said rear inner wall,

a first port for conveying said first portion of liquid to and from said first manifold,

a second port for conveying said second portion of liquid to and from said second manifold; and

means for providing an effective seal of said device within said oral cavity.

[0009] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

[0010] Advantageously the present invention, at least in a preferred form, ameliorates one or more of the above mentioned disadvantages with existing oral hygiene apparatus and methods, or at least provides the market with an alternative technology that is advantageous

over known technology, and also may be used to ameliorate a detrimental condition or to improve cosmetic appearance of the oral cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

[0012] FIG. 1 is a schematic drawing of one embodiment of a system using a device according to the present invention;

[0013] FIG. 2 is a schematic drawing of an alternative embodiment of a system using a device according to the present invention;

[0014] FIG. 3 is a schematic drawing of another alternative embodiment of a system using a device according to the present invention;

[0015] FIG. 4 is a schematic drawing of yet another alternative embodiment of a system using a device according to the present invention;

[0016] FIG. 5 is a schematic drawing of a multiple cleaning solution embodiment of a dental cleaning system using a device according to the present invention;

[0017] FIG. 6a is a perspective drawing of an embodiment of a reciprocating flow controller;

[0018] FIG. 6b is an exploded view of the reciprocating flow controller of FIG 6a;

[0019] FIG. 6c is a cross-sectional view of the reciprocating flow controller of FIG 6a in its first position;

[0020] FIG. 6d is a cross-sectional view of the reciprocating flow controller of FIG 6a in its second position;

[0021] FIG. 7a is a perspective drawing of a first alternative embodiment of a reciprocating flow controller;

[0022] FIG. 7b is a top view of the reciprocating flow controller of FIG 7a in its first position;

[0023] FIG. 7c is a top view of the reciprocating flow controller of FIG 7a in its second position;

[0024] FIG. 8a is an exploded view of a second alternative embodiment of a reciprocating flow controller;

[0025] FIG. 8b is a perspective drawing of the reciprocating flow controller of FIG 8a;

[0026] FIG. 8c is a side view of the reciprocating flow controller of FIG 8a in its first position;

[0027] FIG. 9a is a perspective drawing of a third alternative embodiment of a reciprocating flow controller;

[0028] FIG. 9b is an exploded view of the reciprocating flow controller of FIG 9a;

[0029] FIG. 9c is a top view of the reciprocating flow controller of FIG 9a in its first position;

[0030] FIG. 9d is a top view of the reciprocating flow controller of FIG 9a in its second position;

[0031] FIG. 10a is a perspective drawing of a fourth alternative embodiment of a reciprocating flow controller;

[0032] FIG. 10b is a side view of the reciprocating flow controller of FIG 10a;

[0033] FIG. 10c is a top view of the reciprocating flow controller of FIG 10a in its first position;

[0034] FIG. 10d is a top view of the reciprocating flow controller of FIG 10a in its second position;

[0035] FIG. 11a is a perspective drawing of a fifth alternative embodiment of a reciprocating flow controller;

[0036] FIG. 11b is a top view of the reciprocating flow controller of FIG 11a in its first position;

- [0037] FIG. 11c is a top view of the reciprocating flow controller of FIG 11a in its second position;
- [0038] FIG. 12 is a top front perspective view of a first embodiment of a device according to the present invention;
- [0039] FIG. 13 is a bottom rear perspective view of the embodiment of the device of FIG. 12;
- [0040] FIG. 14 is a vertical sectional view of the device of FIG. 12;
- [0041] FIG. 15 is a horizontal sectional view of the device of FIG. 12;
- [0042] FIG. 16 is a top back perspective view of a second embodiment of with a device according to the present invention;
- [0043] FIG. 17 is a top front perspective view of the embodiment of the device of FIG. 16;
- [0044] FIG. 18 is a top view of the device of FIG. 16;
- [0045] FIG. 19 is a cut-away view of the device of FIG. 16;
- [0046] FIG. 20 is a top front perspective view of a third embodiment of a device according to the present invention;
- [0047] FIG. 21 is a top back view of the embodiment of the device of FIG. 20;
- [0048] FIG. 22 is a bottom back view of the embodiment of the device of FIG. 20;
- [0049] FIG. 23 is a cut-away view of the device of FIG. 20;
- [0050] FIG. 24a is an exploded view of an embodiment of a hand piece;
- [0051] FIG. 24b is an exploded view of the pumping section of the hand piece of FIG. 24a;
- [0052] FIG. 24c is an exploded view of the vacuum section of the hand piece of FIG. 24a;

[0053] FIG. 24d is a side view of the drive system of the pumping and driving sections of the hand piece of FIG. 24a;

[0054] FIG. 24e is a cut-away view of the hand piece of FIG. 24a;

[0055] FIG. 25a is a back, top perspective view of an embodiment of a system including the present invention;

[0056] FIG. 25b is a front, top perspective view of the system of FIG. 25a;

[0057] FIG. 25c is a back, top perspective view of the system of FIG. 25a, with the base station liquid reservoir attached to the base station; and

[0058] FIG. 25d is a front, top perspective view of the system of FIG. 25a, with the base station liquid reservoir attached to the base station.

DETAILED DESCRIPTION OF THE INVENTION

[0059] The terms “reciprocating movement of liquid(s)” and “reciprocation of liquid(s)” are used interchangeably herein. As used herein, both terms mean alternating the direction of flow of the liquid(s) back and forth over surfaces of the oral cavity of a mammal from a first flow direction to a second flow direction that is opposite the first flow direction.

[0060] By “effective fit or seal”, it is meant that the level of sealing between the means for directing liquid onto and about the plurality of surfaces in the oral cavity which forms a part of the device according to the invention, e.g. an application tray or mouthpiece, is such that the amount of leakage of liquid from the device into the oral cavity during use is sufficiently low so as to reduce or minimize the amount of liquid used and to maintain comfort of the user, e.g. to avoid choking or gagging. Without intending to be limited, gagging is understood to be a reflex (i.e. not an intentional movement) muscular contraction of the back of the throat caused by stimulation of the back of the soft palate, the pharyngeal wall, the tonsillar area or base of tongue, meant to be a protective movement that prevents foreign objects from entering the pharynx and into the airway. There is variability in the gag reflex among individuals, e.g. what areas of the mouth stimulate it. In addition to the physical causes of gagging, there may be a psychological element to gagging, e.g. people who have a fear of choking may easily gag when something is placed in the mouth.

[0061] As used herein, "means for conveying liquid" includes structures through which liquid may travel or be transported throughout the systems and devices described herein and includes, without limitation passages, conduits, tubes, ports, portals, channels, lumens, pipes and manifolds. Such means for conveying liquids may be utilized in devices for providing reciprocation of liquids and means for directing liquids onto and about surfaces of the oral cavity. Such conveying means also provide liquid to the directing means and provides liquid to the reciprocation means from a reservoir for containing liquid, whether the reservoir is contained within a hand-held device containing the reciprocation means or a base unit. The conveying means also provides liquid from a base unit to a liquid reservoir contained within the hand-held device. Described herein are methods, devices and systems useful in providing a beneficial effect to an oral cavity of a mammal, e.g. a human.

[0062] Methods entail contacting a plurality of surfaces of the oral cavity with a liquid that is effective for providing the desired beneficial effect to the oral cavity. In such methods, reciprocation of the liquid(s) over the plurality of surfaces of the oral cavity is provided under conditions effective to provide the desired beneficial effect to the oral cavity. Contact of the plurality of surfaces by the liquid may be conducted substantially simultaneous. By substantially simultaneous, it is meant that, while not all of the plurality of surfaces of the oral cavity are necessarily contacted by the fluid at the same time, the majority of the surfaces are contacted simultaneously, or within a short period of time to provide an overall effect similar to that as if all surfaces are contacted at the same time.

[0063] The conditions for providing the desired beneficial effect in the oral cavity may vary depending on the particular environment, circumstances and effect being sought. The different variables are interdependent in that they create a specific velocity of the liquid. The velocity requirement may be a function of the formulation in some embodiments. For example, with change in the viscosity, additives, e.g. abrasives, shear thinning agents, etc., and general flow properties of the formulation, velocity requirements of the jets may change to produce the same level of efficacy. Factors which may be considered in order to provide the appropriate conditions for achieving the particular beneficial effect sought include, without limitation, the velocity and/or flow rate and/or pressure of the liquid stream, pulsation of the liquid, the spray geometry or spray pattern of the liquid, the temperature of the liquid and the frequency of the reciprocating cycle of the liquid.

[0064] The liquid pressures, i.e. manifold pressure just prior to exit through the jets, may be from about 0.5 psi to about 30 psi, or from about 3 to about 15 psi, or about 5 psi. Flow rate of

liquid may be from about 10 ml/s to about 60 ml/s, or about 20 ml/s to about 40 ml/s. It should be noted that the larger and higher quantity of the jets, the greater flow rate required at a given pressure/velocity. Pulse frequency (linked to pulse length and delivery (ml/pulse), may be from about 0.5 Hz to about 50 Hz, or from about 5 Hz to about 25 Hz. Delivery pulse duty cycle may be from about 10% to 100%, or from about 40% to about 60%. It is noted that at 100% there is no pulse, but instead a continuous flow of liquid. Delivery pulse volume (total volume through all jets/nozzles) may be from about 0.2 ml to about 120 ml, or from about 0.5 ml to about 15 ml. Velocity of jetted pulse may be from about 4 cm/s to about 400 cm/s, or from about 20 cm/s to about 160 in/s. Vacuum duty cycle may be from about 10% to 100%, or from about 50% to 100%. It is noted that vacuum is always on at 100%. Volumetric delivery to vacuum ratio may be from about 2:1 to about 1:20, or from about 1:1 to 1:10.

[0065] Once having the benefit of this disclosure, one skilled in the art will recognize that the various factors may be controlled and selected, depending on the particular circumstances and desired benefit sought.

[0066] The liquid(s) will include at least one ingredient, or agent, effective for providing the beneficial effect sought, in an amount effective to provide the beneficial effect when contacted with the surfaces of the oral cavity. For example, the liquid may include, without limitation, an ingredient selected from the group consisting of a cleaning agent, an antimicrobial agent, a mineralization agent, a desensitizing agent and a whitening agent. In certain embodiments, more than one liquid may be used in a single session. For example, a cleaning solution may be applied to the oral cavity, followed by a second solution containing, for example, a whitening agent or an antimicrobial agent. Solutions also may include a plurality of agents to accomplish more than one benefit with a single application. For example, the solution may include both a cleansing agent and an agent for ameliorating a detrimental condition, as further discussed below. In addition, a single solution may be effective to provide more than one beneficial effect to the oral cavity. For example, the solution may include a single agent that both cleans the oral cavity and acts as an antimicrobial, or that both cleans the oral cavity and whitens teeth.

[0067] Liquids useful for improving the cosmetic appearance of the oral cavity may include a whitening agent to whiten teeth in the cavity. Such whitening agents may include, without limitation, hydrogen peroxide and carbamide peroxide, or other agents capable of generating hydrogen peroxide when applied to the teeth. Such agents are well known within the art related to oral care whitening products such as rinses, toothpastes and whitening strips. Other

whitening agents may include abrasives such as silica, sodium bicarbonate, alumina, apatites and bioglass.

[0068] It is noted that, while abrasives may serve to clean and/or whiten the teeth, certain of the abrasives also may serve to ameliorate hypersensitivity of the teeth caused by loss of enamel and exposure of the tubules in the teeth. For example, the particle size, e.g. diameter, of certain of the materials, e.g. bioglass, may be effective to block exposed tubules, thus reducing sensitivity of the teeth.

[0069] In some embodiments, the liquid may comprise an antimicrobial composition containing an alcohol having 3 to 6 carbon atoms. The liquid may be an antimicrobial mouthwash composition, particularly one having reduced ethanol content or being substantially free of ethanol, providing a high level of efficacy in the prevention of plaque, gum disease and bad breath. Noted alcohols having 3 to 6 carbon atoms are aliphatic alcohols. A particularly aliphatic alcohol having 3 carbons is 1-propanol.

[0070] In one embodiment the liquid may comprise an antimicrobial composition comprising (a) an antimicrobial effective amount of thymol and one or more other essential oils, (b) from about 0.01% to about 70.0% v/v, or about 0.1% to about 30% v/v, or about 0.1% to about 10% v/v, or about 0.2% to about 8% v/v, of an alcohol having 3 to 6 carbon atoms and (c) a vehicle. The alcohol may be 1-propanol. The liquid vehicle can be aqueous or non-aqueous, and may include thickening agents or gelling agents to provide the compositions with a particular consistency. Water and water/ethanol mixtures are the preferred vehicle.

[0071] Another embodiment of the liquid is an antimicrobial composition comprising (a) an antimicrobial effective amount of an antimicrobial agent, (b) from about 0.01% to about 70% v/v, or about 0.1% to about 30% v/v, or about 0.2% to about 8% v/v, of propanol and (c) a vehicle. The antimicrobial composition of this embodiment exhibits unexpectedly superior delivery system kinetics compared to prior art ethanolic systems. Exemplary antimicrobial agents which may be employed include, without limitation, essential oils, cetyl pyridium chloride (CPC), chlorhexidine, hexetidine, chitosan, triclosan, domiphen bromide, stannous fluoride, soluble pyrophosphates, metal oxides including but not limited to zinc oxide, peppermint oil, sage oil, sanguinaria, dicalcium dihydrate, aloe vera, polyols, protease, lipase, amylase, and metal salts including but not limited to zinc citrate, and the like. A particularly preferred aspect of this embodiment is directed to an antimicrobial oral composition, e.g. a mouthwash having about 30% v/v or less, or about 10% v/v or less, or about 3% v/v or less, of 1-propanol.

[0072] Yet another embodiment of the liquid is a reduced ethanol, antimicrobial mouthwash composition which comprises (a) an antimicrobial effective amount of thymol and one or more other essential oils; (b) from about 0.01 to about 30.0% v/v, or about 0.1% to about 10% v/v, or about 0.2% to about 8% v/v, of an alcohol having 3 to 6 carbon atoms; (c) ethanol in an amount of about 25% v/v or less; (d) at least one surfactant; and (e) water. Preferably the total concentration of ethanol and alcohol having 3 to 6 carbon atoms is no greater than 30% v/v, or no greater than 25% v/v, or no greater than 22% v/v.

[0073] In still another embodiment, the liquid is an ethanol-free antimicrobial mouthwash composition which comprises (a) an antimicrobial effective amount of thymol and one or more other essential oils; (b) from about 0.01% to about 30.0% v/v, or about 0.1% to about 10% v/v, or about 0.2% to about 8%, of an alcohol having 3 to 6 carbon atoms; (c) at least one surfactant; and (d) water.

[0074] The alcohol having 3 to 6 carbon atoms is preferably selected from the group consisting of 1-propanol, 2-propanol, 1-butanol, 2-butanol, tert-butanol and corresponding diols. 1-Propanol and 2-propanol are preferred, with 1-propanol being most preferred.

[0075] In addition to generally improving the oral hygiene of the oral cavity by cleaning, for example, removal or disruption of plaque build-up, food particles, biofilm, etc., the inventions are useful to ameliorate detrimental conditions within the oral cavity and to improve the cosmetic appearance of the oral cavity, for example whitening of the teeth. Detrimental conditions may include, without limitation, caries, gingivitis, inflammation, symptoms associated with periodontal disease, halitosis, sensitivity of the teeth and fungal infection. The liquids themselves may be in various forms, provided that they have the flow characteristics suitable for use in devices and methods of the present invention. For example, the liquids may be selected from the group consisting of solutions, emulsions and dispersions. In certain embodiments, the liquid may comprise a particulate, e.g. an abrasive, dispersed in a liquid phase, e.g. an aqueous phase. In such cases, the abrasive would be substantially homogeneously dispersed in the aqueous phase in order to be applied to the surfaces of the oral cavity. In other embodiments, an oil-in-water or water-in-oil emulsion may be used. In such cases, the liquid will comprise a discontinuous oil phase substantially homogeneously dispersed within a continuous aqueous phase, or a discontinuous aqueous phase substantially homogeneously dispersed in a continuous oil phase, as the case may be. In still other embodiments, the liquid may be a solution whereby the agent is dissolved in a carrier, or

where the carrier itself may be considered as the agent for providing the desired beneficial effect, e.g., an alcohol or alcohol/water mixture, usually having other agents dissolved therein.

[0076] Disclosed herein are devices, e.g. oral care devices, for example a dental cleaning apparatus, suitable for in-home use and adapted to direct liquid onto a plurality of surfaces of a tooth and/or the gingival area, as well as methods and systems utilizing such devices. In certain embodiments the surfaces of the oral cavity are contacted by the liquid substantially simultaneously. As used herein, reference to the gingival area includes, without limitation, reference to the sub-gingival pocket. The appropriate liquid is directed onto a plurality of surfaces of teeth and/or gingival area substantially simultaneously in a reciprocating action under conditions effective to provide cleaning, and/or general improvement of the cosmetic appearance of the oral cavity and/or amelioration of a detrimental condition of the teeth and/or gingival area, thereby providing generally improved oral hygiene of teeth and/or gingival area. For example, one such device cleans teeth and/or the gingival area and removes plaque using an appropriate cleaning liquid by reciprocating the liquid back and forth over the front and back surfaces and inter-proximal areas of the teeth, thereby creating a cleaning cycle while minimizing the amount of cleaning liquid used.

[0077] Devices that provide reciprocation of the liquid comprise a means for controlling reciprocation of the liquid. The controlling means include means for conveying the liquid to and from a means for directing the liquid onto the plurality of surfaces of the oral cavity. In certain embodiments, the means for providing reciprocation of the liquid comprises a plurality of portals for receiving and discharging the liquid, a plurality of passages, or conduits, through which the liquid is conveyed, and means for changing the direction of flow of the liquid to provide reciprocation of the liquid, as described in more detail herein below. The controlling means may be controlled by a logic circuit and/or a mechanically controlled circuit.

[0078] In certain embodiments, devices for providing reciprocation may include a means for attaching or connecting the device to a reservoir for containing the liquid. The reservoir may be removably attached to the device. In this case, the reservoir and the device may comprise means for attaching one to the other. After completion of the process, the reservoir may be discarded and replaced with a different reservoir, or may be refilled and used again. In other embodiments, the reciprocating device will include a reservoir integral with the device. In embodiments where the device may be attached to a base unit, as described herein, the reservoir, whether integral with the device or removably attached to the device, may be refilled

from a supply reservoir which forms a part of the base unit. Where a base unit is utilized, the device and the base unit will comprise means for attaching one to the other.

[0079] The device will comprise a power source for driving the means for reciprocating liquids. The power source may be contained within the device, e.g. in the handle of the device, for example, batteries, whether rechargeable or disposable. Where a base unit is employed, the base may include means for providing power to the device. In other embodiments, the base unit may include means for recharging the rechargeable batteries contained within the device.

[0080] Devices for providing reciprocation of liquids will include means for attaching the device to means for directing the liquid onto the plurality of surfaces of the oral cavity, e.g. application tray or mouthpiece according to the invention. In certain embodiments, the directing means provides substantially simultaneous contact of the plurality of surfaces of the oral cavity by the liquid. The attachment means may provide removable attachment of the tray or mouthpiece to the device. In such embodiments, multiple users may use their own mouthpiece with the single device comprising the reciprocating means. In other embodiments, the attachment means may provide a non-removable attachment to the mouthpiece, whereby the mouthpiece is an integral part of the device. Devices for providing reciprocation as described above may be contained within a housing also containing other device components so as to provide a hand-held device suitable for providing liquid to the directing means, as described herein below.

[0081] Devices of the present invention comprise a chamber for maintaining the liquid proximate the plurality of surfaces, i.e. liquid-contacting-chamber (LCC). By "proximate", it is meant that the liquid is maintained in contact with the surfaces. The LCC is defined by the space bounded by the front inner wall and rear inner wall of the mouthpiece, and a wall, or membrane, extending between and integral with the front and rear inner walls of the mouthpiece, and in certain embodiments, a rear gum-sealing membrane. Together, the front and rear inner walls, the wall extending there between and rear gum-sealing membrane form the LCC membrane (LCCM). The general shape of the LCCM is that of a "U" or an "n", depending on the orientation of the mouthpiece, which follows the teeth to provide uniform and optimized contact by the liquid. The LCCM may be flexible or rigid depending on the particular directing means. The membrane may be located as a base membrane of the LCCM. The front and rear inner walls of the LCCM each include a plurality of openings, or slots, through which the liquid is directed to contact the plurality of surfaces of the oral cavity.

[0082] The LCCM design may be optimized for maximum effectiveness as it relates to the size, shape, thickness, materials, volume created around the teeth/gingiva, nozzle design and placement as it relates to the oral cavity and the teeth in conjunction with the manifold and gingival margin seal to provide comfort and minimize the gagging reflex of the user. The combination of the above provides effective contact of the teeth and gingival area by the liquid.

[0083] The LCCM provides a controlled and isolated environment with known volume, i.e. the LCC, to contact teeth and/or gingival area with liquids, and then to remove spent liquids, as well as debris, plaque, etc., from the LCC without exposing the whole oral cavity to liquid, debris, etc. This decreases the potential for ingestion of the liquids. The LCCM also allows increased flow rates and pressure of liquids without drowning the individual nozzles when significant flow rates are required to provide adequate cleaning, for example. The LCCM also allows reduced liquid quantities and flow rates when required, as only the area within the LCC is being contacted with liquid, not the entire oral cavity. The LCCM also allows controlled delivery and duration of contact of liquid on, through and around teeth and the gingival area, allowing increased concentrations of liquids on the area being contacted by the liquid, thereby providing more effective control and delivery of liquid.

[0084] The thickness of the walls of the LCCM may be within a range of 0.2 mm to 1.5 mm, to provide necessary physical performance properties, while minimizing material content, and optimizing performance. The distance between the inner walls of the LCCM to the teeth may be from about 0.1 mm to about 5 mm, and more typically an average distance of about 2.5 mm to provide maximum comfort, while minimizing customization and LCC volume requirements.

[0085] The size and shape of the mouthpiece preferably utilizes three basic universal sizes (small, medium and large) for both the top and bottom teeth, but the design provides mechanisms to allow different levels of customization as required to ensure comfort and functionality to the individual user. The device may incorporate a switching mechanism, which would allow it to be operable only when in the correct position in the mouth. The mouthpiece may include both upper and lower sections to provide substantially simultaneous contact of the plurality of surfaces of the oral cavity by liquid. In an alternate embodiment the upper and lower sections may be cleaned utilizing a single bridge that could be used on the upper or lower teeth and gums of the user (first placed one portion for cleaning, then subsequently placed over the other portion for cleaning).

[0086] The number and location of openings, also referred to herein as slots, jets or nozzles, contained within the inner walls of the mouthpiece through which the liquid is directed will vary and be determined based upon the circumstances and environment of use, the particular user and the beneficial effect being sought. The cross-sectional geometry of the openings may be circular, elliptical, trapezoidal, or any other geometry that provides effective contact of the surfaces of the oral cavity by the liquid. The location and number of openings may be designed to direct jets of liquid in a variety of spray patterns effective for providing the desired beneficial effect. Opening diameters may be from about 0.1 to about 3 mm, or from about 0.2 mm to about 0.8 mm, or about 0.5 mm, to provide effective cleaning and average jet velocities and coverage.

[0087] Optimal opening placement and direction/angles allows coverage of substantially all teeth surfaces in the area of the oral cavity to be contacted by liquid, including but not limited to interdental, top, side, back, and gingival pocket surfaces. In alternate embodiments, the openings could be of different sizes and different shapes to provide different cleaning, coverage and spray patterns, to adjust velocities, density and fan patterns (full cone, fan, partial, cone, jet), or due to formulation consideration. Nozzles could also be designed to be tubular and or extend from the LCC membrane to provide directed spray, or act as sprinkler like mechanism to provide extended coverage across the teeth, similar to a hose sprinkler system. The nozzles are preferably integral to the inner walls of the LCC membrane and can be incorporated into the inner walls through any number of assembly or forming techniques known in the art (insert molded, formed in membrane through machining, injection molding, etc.).

[0088] The LCCM may be an elastomeric material such as ethylene vinyl acetate (EVA), thermoplastic elastomer (TPE), or silicone, to allow motion of the inner walls and provide a greater jet coverage area with minimal mechanics, reducing the volumetric flow requirements to achieve optimized performance, while providing a softer and more flexible material to protect the teeth if direct contact with the teeth is made. A flexible membrane may also provide acceptable fitment over a large range of users, due to its ability to conform to the teeth. Alternatively, the LCCM could be made of a rigid or semi-rigid material, such as but not limited to a thermoplastic.

[0089] In an alternate embodiment, the LCCM could also include abrasive elements such as filaments, textures, polishing elements, additives (silica, etc.), and other geometric elements that could be used for other cleaning and/or treatment requirements as well as ensuring

minimal distance between the teeth and LCCM for, but not limited to, treatment, cleaning, and positioning.

[0090] The LCCM could be created via a variety of methods such as, but not limited to, machining, injection molding, blow molding, extrusion, compression molding, and/or vacuum forming. It can also be created in conjunction with the manifold, but incorporating the manifold circuitry within the LCC, and/or over-molded onto the manifold to provide a unitary construction with minimal assembly.

[0091] In one embodiment, the LCCM may be fabricated separately and then assembled to the manifolds, utilizing any number of assembling and sealing techniques, including adhesives, epoxies, silicones, heat sealing, ultrasonic welding, and hot glue. The LCCM is designed in a way that, when assembled with the manifold, it effectively and efficiently creates the preferred dual manifold design without any additional components.

[0092] In certain embodiments, the LCCM can also be designed or used to create the gingival sealing area. In certain embodiments, a vacuum is applied within the LCC, which improves the engagement of the mouthpiece to form a positive seal with the gingival in the oral cavity. In other embodiments, a pressure is applied outside the LCCM, within the oral cavity, which improves the engagement of the mouthpiece to form a positive seal with the gingival in the oral cavity. In yet other embodiments, a denture-like adhesive may be applied around the mouthpiece during the initial use to provide a custom reusable resilient seal when inserted into the oral cavity for a particular user. It would then become resiliently rigid to both conform and provide a positive seal with the gums and on subsequent applications. In another embodiment, the seal could be applied and/or replaced or disposed of after each use.

[0093] Devices of the invention also comprise a first manifold for containing the liquid and for providing the liquid to the LCC through the openings of the front inner wall, and a second manifold for containing the liquid and for providing the liquid to the chamber through the openings of the rear inner wall. This design provides a number of different options, depending on what operation is being conducted. For instance, in a cleaning operation, it may be preferable to deliver jets of liquid into the LCC directly onto the teeth from one side of the LCC from the first manifold and then evacuate/pull the liquid around the teeth from the other side of the LCC into the second manifold to provide controlled interdental, gumline and surface cleaning. This flow from the one side of the LCC could be repeated a number of times in a pulsing action before reversing the flow to deliver jets of liquid from the second manifold and

evacuating/pulling the liquid through the back side of the teeth into the first manifold for a period of time and/or number of cycles. Such liquid action creates a turbulent, repeatable and reversible flow, thus providing reciprocation of the liquid about the surfaces of the oral cavity.

[0094] In alternate embodiments, the manifold can be of single manifold design providing pushing and pulling of the liquid through the same sets of jets simultaneously, or can be any number of manifold divisions to provide even greater control of the liquid delivery and removal of the cleaning and liquid treatment. In the multi-manifold also can be designed to have dedicated delivery and removal manifolds. The manifolds can also be designed to be integral to and/or within the LCCM.

[0095] The material for the manifold would be a semi-rigid thermoplastic, which would provide the rigidity necessary not to collapse or burst during the controlled flow of the liquids, but to provide some flexibility when fitting within the user's mouth for mouthpiece insertion, sealing/position and removal. To minimize fabrication complexity, number of components and tooling cost, the dual manifold is created when assembled with the LCCM. The manifold could also be multi-component to provide a softer external "feel" to the teeth/gums utilizing a lower durometer elastomeric material, such as, but not limited to, a compatible thermoplastic elastomer (TPE). The manifold could be created via a variety of methods such as, but not limited to machining, injection molding, blow molding, compression molding, or vacuum forming.

[0096] Devices of the invention also comprise a first port for conveying the liquid to and from the first manifold and a second port for conveying the liquid to and from the second manifold, and means for providing an effective seal of the directing means within the oral cavity, i.e. a gingival seal. In certain embodiments, the first and second ports may serve both to convey liquid to and from the first and second manifolds and to attach the mouthpiece to the means for providing liquid to the mouthpiece. In other embodiments, the directing means may further include means for attaching the directing means to means for providing liquid to the directing means.

[0097] FIG. 1 is a schematic drawing of an embodiment of a system utilizing devices according to the present invention. The figure shows system **200**, with components including: means for providing reciprocation of liquid in the oral cavity **202**, means for directing the liquid onto the plurality of surfaces of the oral cavity, in this instance shown as application tray **100**, and liquid supply reservoir **290**. Means for providing reciprocation of liquids may include, in this

embodiment, delivery/collection device **210**, reciprocating flow controller **230**, tubes **212**, **216**, and **292** for conveying the liquid throughout the system, and liquid one-way flow valves **214**, **218** and **294**. Tubes **232** and **234** provide for conveyance of the liquid from reciprocating flow controller **230** to application tray **100**.

[0098] In some embodiments, delivery/collection device **210** may be a piston pump. Liquid supply reservoir **290** may be made of glass, plastic or metal. Liquid supply reservoir **290** may be integral to system **200** and refillable. In some embodiments, liquid supply reservoir **290** may be a replaceable liquid supply, such as a single or multi-use cartridge, detachably connected to system **200**.

[0099] In some embodiments, liquid supply reservoir **290** and/or tubes **212**, **292**, may include a heat source to pre-warm the liquid prior to direction into application tray **100** for application to the surfaces of the oral cavity. The temperature should be maintained within a range effective to provide efficacy and comfort to the user during use.

[0100] Application tray **100**, discussed in detail herein below, could be integral with, or detachably connected to reciprocating means **202** by way of tubes **232**, **234** and further attachment means (not shown). It could be one or two sided with internally, easily cleanable filters for trapping food particles. When positioned within the oral cavity, e.g. about the teeth and gums, tray **100** forms an effective fit or seal against the gums, and includes means to direct liquid against surfaces of the oral cavity, e.g. surfaces of the teeth.

[0101] Liquid in liquid supply reservoir **290** flows through tube **292** to delivery/collection device **210**. Liquid flow through tube **292** is controlled by one-way flow valve **294**. From delivery/collection device **210**, liquid flows through tube **212** to reciprocating flow controller **230**. One-way flow valve **214** controls the liquid flow through tube **212**. Liquid flows from reciprocating flow controller **230** to application tray **100** either through tube **232** or **234**, depending on the flow direction setting of flow controller **230**. Liquid flows from application tray **100**, through either tube **234** or **232** back to reciprocating flow controller **230**, and from reciprocating flow controller **230** to delivery/collection device **210**, through tube **216**. One-way flow valve **218** controls the liquid flow through tube **216**.

[0102] The actions of delivery/collection device **210** may be controlled by a logic circuit, which may include a program to start the reciprocation cycle, a program to execute the reciprocation cycle, i.e. to cause liquid to be reciprocated about the teeth, thereby providing the

beneficial effect to the oral cavity, e.g. cleaning the teeth, a program to empty application tray **100** at the end of the reciprocation cycle, and a self-cleaning cycle to clean the system between uses, or at pre-set or automatic cleaning times.

[0103] Though not shown, a face panel with a series of switches and indicator lights may also be incorporated into system **200**. Switches may include, but are not limited to, on/off, fill application tray **100**, run the reciprocation program, empty system **200**, and clean system **200**. Indicator, or display, lights include, but are not limited to, power on, charging, reciprocation program running, system emptying, cleaning results or feedback, and self-cleaning cycle in operation. In embodiments where liquid is pre-warmed prior to direction into application tray **100**, a display light could be used to indicate that the liquid is at the proper temperature for use.

[0104] One method of using system **200** to clean teeth is as follows. In the first step, the user positions application tray **100** in the oral cavity about the teeth and gingival area. The user closes down on tray **100**, thereby achieving an effective fit or seal between gums, teeth and tray **100**. In use of the system according to the invention, the user pushes a start button initiating the cleaning process. The cleaning process is as follows:

1. Delivery/collection device **210** is activated to begin drawing cleaning liquid from liquid supply reservoir **290** through tube **292** and one-way valve **294**.
2. Once delivery/collection device **210** is sufficiently filled, delivery/collection device **210** is activated to begin dispensing cleaning liquid to application tray **100** via tube **212**, one-way valve **214**, reciprocating flow controller **230**, and tube **232**. Cleaning liquid will be prevented from flowing through tubes **216** and **292** by one-way flow valves **218** and **294**, respectively.
3. Delivery/collection device **210** is activated to begin drawing cleaning liquid from application tray **100** through tube **234**, then through reciprocation flow controller **230**, then through tube **216** and one-way valve **218**. Cleaning liquid will be prevented from flowing through tube **212** by one-way flow valve **214**. If there is insufficient cleaning liquid to adequately fill delivery/collection device **210**, additional cleaning liquid may be drawn from liquid supply reservoir **290** through tube **292** and one-way valve **294**.
4. The direction of the liquid flow is then reversed.
5. To reciprocate the cleaning liquid, steps 2 and 3 are repeated after the flow direction is reversed, cycling cleaning liquid between delivery/collection device **210** and application tray **100**, using tubes **234** and **232**, respectively.

6. The reciprocation cycle described continues until the time required for cleaning has expired, or the desired numbers of cycles are complete.

[0105] It is noted that there may be a delay between steps 2 and 3 (in either or both, directions), allowing a dwell time where the liquid is allowed to contact the teeth without flow.

[0106] FIG. 2 is a schematic drawing of a first alternative embodiment of a system utilizing devices according to the present invention. The figure shows system **300**, with components including: means for providing reciprocation of liquid in the oral cavity **302**, liquid reservoir **370**, liquid supply reservoir **390**, and means for directing liquid onto and about the plurality of surfaces in the oral cavity, in this instance shown as application tray **100**. Means for providing reciprocation of fluids may include delivery device **310**, collection device **320**, reciprocating flow controller **330**, tubes **312**, **322**, **372**, **376**, and **392**, and solution one-way flow valves **314**, **324**, **374**, **378**, and **394**. Tubes **332** and **334** provide for conveyance of the liquid from reciprocating flow controller **330** to application tray **100**.

[0107] In some embodiments, delivery device **310** and collection device **320** may be individual, single action piston pump. In other embodiments, delivery device **310** and collection device **320** may be housed together as a dual action piston pump. Liquid supply reservoir **390** and liquid reservoir **370** may be made of glass, plastic or metal. Liquid supply reservoir **390** may be integral to system **300** and refillable. In some embodiments, liquid supply reservoir **390** may be a replaceable liquid supply, detachably connected to system **300**.

[0108] In some embodiments, any of liquid supply reservoir **390**, liquid reservoir **370**, or tubes **312**, **372**, **392**, may include a heat source to pre-warm liquid prior to direction into application tray **100** for application to the plurality of surfaces in the oral cavity. The temperature should be maintained within a range effective to provide comfort to the user during use.

[0109] Application tray **100**, could be integral with, or detachably connected to cleaning reciprocating means **302** by way of tubes **332**, **334**, and other attachment means (not shown).

[0110] Liquid in liquid supply reservoir **390** flows through tube **392** to liquid reservoir **370**. Liquid in reservoir **370** flows through tube **372** to delivery device **310**. Liquid flow through tube **372** may be controlled by one-way flow valve **374**. From delivery device **310**, liquid flows through tube **312** to reciprocating flow controller **330**. One-way flow valve **314** controls the

liquid flow through tube **312**. Liquid flows from reciprocating flow controller **330** to application tray **100** through tube **332** or **334**, depending on the flow direction setting of flow controller **330**. Liquid flows from application tray **100**, through tube **334** or **332** back to reciprocating flow controller **330**, and from reciprocating flow controller **330** to collection device **320**, through tube **322**. One-way flow valve **324** controls the liquid flow through tube **322**. Finally, cleaning liquid flows from collection device **320** to liquid reservoir **370** through tube **376**. One-way flow valve **378** controls the liquid flow through tube **376**.

[0111] The actions of delivery device **310** and collection device **320** are controlled by a logic circuit, which may include a program to the start of the reciprocation cycle, a program to execute the reciprocation cycle, i.e. to cause solution to be reciprocated about the plurality of surfaces of the oral cavity, thereby providing the beneficial effect, a program to empty application tray **100** at the end of the reciprocation cycle, and a self-cleaning cycle to clean the system between uses, or at pre-set or automatic cleaning times.

[0112] System **300** may also include switches such as on/off, fill application tray **100**, run the cleaning program, empty system **300**, and clean system **300**, and indicator, or display, lights including, but are not limited to, power on, charging, cycle program running, device emptying, results or feedback, and self-cleaning cycle in operation. In embodiments where liquid is pre-warmed prior to direction into application tray **100**, a display light could be used to indicate that the liquid is at the proper temperature for use.

[0113] One method of using system **300** to clean teeth is as follows. Prior to use, cleaning liquid in liquid supply chamber **390** flows through tube **392** and one-way valve **394** to cleaning liquid reservoir **370**. In some embodiments, liquid supply reservoir **390** is now disconnected from system **300**.

[0114] In the first step, the user positions application tray **100** in the oral cavity about the teeth and gingival area. The user closes down on tray **100**, thereby achieving an effective fit or seal between gums, teeth and tray **100**. The user pushes a start button initiating the cleaning process. The cleaning process is as follows:

1. Delivery device **310** is activated to begin drawing cleaning liquid from cleaning liquid reservoir **370** through tube **372** and one-way flow valve **374**.

2. Once delivery device **310** is sufficiently filled, delivery device **310** is activated to begin dispensing cleaning liquid to application tray **100** via tube **312**, one-way valve **314**, reciprocating flow controller **330**, and tube **332**.
3. Collection device **320** is activated sequentially to, or simultaneously with, activation of delivery device **310** to begin drawing cleaning liquid from application tray **100** via tube **334**, reciprocating flow controller **330**, tube **322**, and one-way valve **324**. Cleaning solution will be prevented from flowing through tube **372** by one-way flow valve **374**. In some embodiments, delivery device **310** and collection device **320** are controlled by a logic circuit to work in concert so that an equal volumetric flow of cleaning liquid is dispensed from delivery device **310** and drawn into collection device **320**.
4. Collection device **320** is activated to begin dispensing cleaning solution to cleaning liquid reservoir **370** via tube **376** and one-way valve **378**. Cleaning liquid will be prevented from flowing through tube **322** by one-way flow valve **324**. Delivery device **310** is also activated to begin drawing cleaning liquid from cleaning liquid reservoir **370** through tube **372** and one-way flow valve **374**.
5. To reciprocate the cleaning liquid, steps 2 and 3 are repeated after the flow direction is reversed, cycling cleaning liquid between delivery/collection device **320** and application tray **100**, using tubes **334** and **332**, respectively.
6. To cycle cleaning liquid, steps 2 through 4 are repeated, cycling cleaning liquid between cleaning liquid reservoir **370** and application tray **100**.
7. The process continues to run until the time required for cleaning has expired, or the desired numbers of cycles are complete.

[0115] FIG. 3 is a schematic drawing of a second alternative embodiment of a system utilizing devices according to the present invention. The figure shows system **400**, with components including: means for providing reciprocation of liquids in the oral cavity **402**, liquid reservoir **470**, liquid supply reservoir **490**, and means for directing the liquid onto the plurality of surfaces of the oral cavity, in this instance shown as application tray **100**. Means for providing reciprocation **402** may include delivery device **410**, collection device **420**, reciprocating flow controller **430**, tubes **412**, **422a**, **422b**, **472**, **476**, and **492**, and solution one-way flow valves **414**, **424a**, **424b**, **474**, **478a**, **478b**, and **494**. Tubes **432** and **434** provide for conveyance of the liquid from reciprocating flow controller **430** to application tray **100**.

[0116] In the present embodiment, delivery device **410** and collection device **420** are housed together as a dual action piston pump, with common piston **415**. Liquid supply reservoir **490** and liquid reservoir **470** may be made of glass, plastic, or metal. Liquid supply

reservoir **490** may be integral to system **400** and refillable. In some embodiments, liquid supply chamber **490** may be a replaceable liquid supply, detachably connected to system **400**.

[0117] In some embodiments, any of liquid supply chamber **490**, liquid reservoir **470**, or tubes **412**, **472**, **492**, may include a heat source to pre-warm cleaning solution prior to direction into application tray **100** for application to the teeth. The temperature should be maintained within a range effective to provide comfort to the user during use.

[0118] Application tray **100** could be integral with, or detachably connected to reciprocating means **402** by way of tubes **432**, **434** and other attachment means (not shown).

[0119] Liquid in liquid supply chamber **490** flows through tube **492** to liquid reservoir **470**. Liquid in reservoir **470** flows through tube **472** to delivery device **410**. Liquid flow through tube **472** is controlled by one-way flow valve **474**. From delivery device **410**, liquid flows through tube **412** to reciprocating flow controller **430**. One-way flow valve **414** controls the liquid flow through tube **412**. Liquid flows from reciprocating flow controller **430** to application tray **100** through tube **432** or tube **434**, depending on the flow direction. Liquid flows from application tray **100**, through tube **434** or tube **432**, again depending on the flow direction, back to reciprocating flow controller **430**, and from reciprocating flow controller **430** to collection device **420**, through tubes **422a** and **422b**. One-way flow valves **424a** and **424b** control the liquid flow through the tubes. Finally, liquid flows from collection device **420** to liquid reservoir **470** through tubes **476a** and **476b**. One-way flow valves **478a** and **478b** control the liquid flow through the tubes.

[0120] The actions of delivery device **410** and collection device **420** are controlled by a logic circuit, which may include a program to the start reciprocation cycle, a program to execute the reciprocation cycle, i.e. to cause solution to be reciprocated about the plurality of the surfaces of the oral cavity, thereby providing the beneficial effect, a program to empty application tray **100** at the end of the cycle, and a self-cleaning cycle to clean the system between uses, or at pre-set or automatic cleaning times.

[0121] System **400** may also include switches such as on/off, fill application tray **100**, execute cleaning process, empty system **400**, and clean system **400**, and indicator, or display, lights including, but are not limited to, power on, charging, reciprocation program running, device emptying, and self-cleaning cycle in operation. In embodiments where liquid is pre-

warmed prior to direction into application tray **100**, a display light could be used to indicate that the liquid is at the proper temperature for use.

[0122] One method of using system **400** to clean teeth is as follows. Prior to use, cleaning liquid in liquid supply reservoir **490** flows through tube **492** and one-way valve **494** to cleaning liquid reservoir **470**. In some embodiments, liquid supply reservoir **490** is now disconnected from system **400**.

[0123] In the first step, the user positions application tray **100** in the oral cavity about the teeth and gingival area. The user closes down on tray **100**, thereby achieving an effective fit or seal between gums, teeth and tray **100**. The user pushes a start button initiating the cleaning process. The cleaning process is as follows:

1. Piston **415** is activated to begin drawing cleaning liquid to delivery device **410** from cleaning liquid reservoir **470** through tube **472** and one-way flow valve **474**. To accomplish this, piston **415** translates from right to left ("R" to "L" on FIG. 3).
2. Once delivery device **410** is sufficiently filled, delivery device **410** is activated to begin dispensing cleaning liquid to application tray **100** via tube **412**, one-way valve **414**, reciprocating flow controller **430**, and tube **432**. To accomplish this, piston **415** translates from left to right ("L" to "R" on FIG. 3). The "L" to "R" motion of piston **415** causes collection device **420** to begin drawing cleaning liquid from application tray **100** via tube **434**, reciprocating flow controller **430**, tube **422a**, and one-way valve **424a**. Cleaning liquid will be prevented from flowing through tubes **472** and **422a**, by one-way flow valves **474** and **424b**. Any excess cleaning liquid in collection device **420** will begin dispensing to cleaning liquid reservoir **470** via tube **476b** and one-way valve **478b**. Cleaning liquid will be prevented from flowing through tube **422b** by one-way flow valve **424b**.
3. To cycle cleaning solution, steps 1 and 2 are repeated, cycling cleaning liquid between cleaning solution reservoir **470** and application tray **100**
4. The process continues to run until the time required for cleaning has expired, or the desired numbers of cycles are complete.

[0124] Each embodiment described in FIG. 1, FIG. 2, and FIG. 3 includes reciprocating flow controller (**230**, **330**, **430** in FIG. 1, FIG. 2, FIG. 3, respectively). A perspective drawing and an exploded view of an embodiment of a reciprocating flow controller according to the present invention is shown in FIG. 6a and FIG. 6b, respectively. The figures show reciprocating flow controller **500** with housing **510** and flow diverter **520**. Housing **510** has ports **514**, **515**, **516**,

and **517**. Flow diverter **520** occupies the space defined by the inner walls of housing **510**, and has panel **522** for diverting liquid flow, and position adjuster **524**.

[0125] FIG. 6c is a cross-sectional view of reciprocating flow controller **500** in its first position. In this position, incoming liquid flow **532**, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **500** through port **515**. The liquid exits reciprocating flow controller **500** through port **514** as outgoing liquid flow **534**, or as liquid in tube **232** of FIG. 1. Returning liquid flow **536**, such as liquid in tube **234** of FIG. 1, reenters reciprocating flow controller **500** through port **517**. The liquid re-exits reciprocating flow controller **500** through port **516** as outgoing liquid flow **538**, or as liquid in tube **216** of FIG. 1.

[0126] FIG. 6d is a cross-sectional view of the reciprocating flow controller **500** in its second position. In this position, incoming liquid flow **532**, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **500** through port **515**. The liquid exits reciprocating flow controller **500** through port **516** as outgoing liquid flow **534**, or as liquid in tube **234** of FIG. 1. Returning liquid flow **536**, such as liquid in tube **232** of FIG. 1, reenters reciprocating flow controller **500** through port **517**. The liquid re-exits reciprocating flow controller **500** through port **514** as outgoing liquid flow **538**, or as liquid in tube **216** of FIG. 1.

[0127] Reciprocation of liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **500** between its first and second positions.

[0128] A perspective drawing of a first alternative embodiment of a reciprocating flow controller is shown in FIG. 7a. The figure shows reciprocating flow controller **550** with housing **560**, flow control block **570**, and set pin **580**. Housing **560** has ports **564**, **565**, **566**, and **567**. Flow control block **570** occupies the space defined by the inner walls of housing **560**, and has passages, or conduits, **571**, **572**, **573**, and **574** for diverting liquid flow.

[0129] FIG. 7b is a top view of reciprocating flow controller **550** in its first position (set pin **580** in "out" position). In first position, incoming liquid flow **592**, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **550** through port **564**. The liquid flows through passage **573** of control block **570**, and exits reciprocating flow controller **550** through port **566** as outgoing liquid flow **594**, or as liquid in tube **232** of FIG. 1. Returning liquid flow **596**, such as cleaning liquid in tube **234** of FIG. 1, reenters reciprocating flow controller **550** through port **567**. The liquid flows through passage **571** of control block **570**, and exits reciprocating flow controller **550** through port **565** as outgoing liquid flow **598**, or as liquid in tube **216** of FIG. 1.

[0130] FIG. 7c is a top view of reciprocating flow controller **550** in its second position (set pin **580** in "in" position). In second position, incoming liquid flow **592**, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **550** through port **564**. The liquid flows through passage **574** of control block **570**, and exits reciprocating flow controller **550** through port **567** as outgoing liquid flow **594**, or as liquid in tube **234** of FIG. 1. Returning liquid flow **596**, such as liquid in tube **232** of FIG. 1, reenters reciprocating flow controller **550** through port **566**. The liquid flows through passage **572** of control block **570**, and exits reciprocating flow controller **550** through port **565** as outgoing liquid flow **598**, or as liquid in tube **212** of FIG. 1.

[0131] Reciprocation of liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **550** between its first and second positions.

[0132] An exploded view, as well as a perspective view of a second alternative embodiment of a reciprocating flow controller is shown in FIG. 8a and FIG. 8b, respectively. The figures show reciprocating flow controller **610** with housing **620** and flow control barrel **630**. Housing **620** has ports **621**, **622**, **623**, and **624**. Flow control barrel **630** occupies the space defined by the inner walls of housing **620**, has passages **633**, **634**, **635**, and **636** for diverting liquid flow, and position adjuster **632**.

[0133] FIG. 8c is a side view of reciprocating flow controller **610** in its first position. In the first position, incoming liquid enters reciprocating flow controller **610** through port **621**. The liquid flows through passage **634** of control barrel **630**, and exits reciprocating flow controller **610** through port **623**. Returning liquid reenters reciprocating flow controller **610** through port **624**. The liquid flows through passage **633** of control barrel **630**, and exits reciprocating flow controller **610** through port **622**.

[0134] Though not shown, reciprocating flow controller **610** may be placed in its second position by rotating position adjuster **632** by 90°. In second position, incoming liquid enters reciprocating flow controller **610** through port **621**. The liquid flows through passage **636** of control barrel **630**, and exits reciprocating flow controller **610** through port **624**. Returning liquid reenters reciprocating flow controller **610** through port **623**. The liquid flows through passage **636** of control barrel **630**, and exits reciprocating flow controller **610** through port **622**.

[0135] Reciprocation of liquid in application tray **100** of FIGs. 1, 2 or 3 is achieved by switching reciprocating flow controller **610** between its first and second positions.

[0136] A perspective drawing and an exploded view of a third alternate embodiment of a reciprocating flow controller is shown in FIG. 9a and FIG. 9b, respectively. The figures show reciprocating flow controller **710** with cap **720**, flow diverter disk **730**, and base **740**. Cap **720** has cap ports **722** and **724**. Base **740** has base ports **742** and **744**. Flow diverter disk **730** is disposed between cap **720** and base **740**, and has panel **735** for diverting liquid flow, and position adjuster **732** in the form of a gear.

[0137] FIG. 9c is a top view of reciprocating flow controller **710** in its first position. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **710** through base port **742**. The liquid exits reciprocating flow controller **710** through cap port **722**, such as liquid in tube **232** of FIG. 1. Returning liquid, such as liquid in tube **234** of FIG. 1, reenters reciprocating flow controller **710** through cap port **724**. The liquid re-exits reciprocating flow controller **710** through base port **744**, such as liquid in tube **216** of FIG. 1.

[0138] FIG. 9d is a top view of the reciprocating flow controller **710** in its second position. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **710** through base port **742**. The liquid exits reciprocating flow controller **710** through cap port **724** such as liquid in tube **234** of FIG. 1. Returning liquid, such as liquid in tube **232** of FIG. 1, reenters reciprocating flow controller **710** through cap port **722**. The liquid exits reciprocating flow controller **710** through base port **744**, such as liquid in tube **216** of FIG. 1.

[0139] Reciprocation of liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **710** between its first and second positions. It has been found that the width of panel **735** relative to the diameters of cap ports **722** and **724** and base ports **742** and **744** is critical to the performance of reciprocating flow controller **710**. If the width of panel **735** is equal to or greater than any of the diameters, then one or more of cap ports **722** and **724** or base ports **742** and **744** may be blocked, or isolated, during part of the reciprocation, resulting in suboptimal performance or device failure. A channel may be located in panel **735** to avoid this condition.

[0140] A perspective drawing and a side view of a fourth alternate embodiment of a reciprocating flow controller is shown in FIG. 10a and FIG. 10b, respectively. The figures show reciprocating flow controller **750** with cap **760**, flow diverter **770**, and base **780**. Cap **760** has cap ports **762** and **764**. Base **780** has base top ports **781**, **782**, **784**, and **785**, as well as base bottom ports **783** and **786**. Base top ports **781** and **782** merge to form base bottom port **783**, while base top ports **784** and **785** merge to form base bottom port **786**. Flow diverter **770** is

disposed between cap **760** and base **780**, and has twin gears **770a** and **770b** for diverting liquid flow.

[0141] FIG. 10c is a top view of reciprocating flow controller **750** in its first position. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **750** through base bottom port **783**, while base top port **784** is blocked. Gear **770a** is set so that the liquid exits base **780** through base top port **781**. The liquid exits reciprocating flow controller **750** through cap port **762**, such as liquid in tube **232** of FIG. 1. Returning liquid, such as liquid in tube **234** of FIG. 1, reenters reciprocating flow controller **750** through cap port **764**. Gear **770b** is set so that the liquid enters base **780** through base top port **785**. The liquid exits reciprocating flow controller **750** through base port **786**, such as liquid in tube **216** of FIG. 1.

[0142] FIG. 10d is a top view the reciprocating flow controller **750** in its second position. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **750** through base port **783**. Gear **770b** is set so that the liquid exits base **780** through base top port **782**, while base top port **785** is blocked. The liquid exits reciprocating flow controller **710** through cap port **764** such as liquid in tube **234** of FIG. 1. Returning liquid, such as liquid in tube **232** of FIG. 1, reenters reciprocating flow controller **750** through cap port **762**. Gear **770a** is set so that the liquid enters base **780** through base top port **784**, while base top port **781** is blocked. The liquid exits reciprocating flow controller **750** through base port **786**, such as liquid in tube **216** of FIG. 1.

[0143] Reciprocation of liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **750** between its first and second positions. When between the first and second positions, flow cross-over is allowed to eliminate blocked flow, which could result in sub-optimal operation or device failure.

[0144] A perspective drawing of a fifth alternate embodiment of a reciprocating flow controller is shown in FIG. 11a. The figure shows reciprocating flow controller **810** with flow channels **831**, **832**, **833**, **834**, **835**, **836**, **837**, and **838**, and flow diverter **820**. Flow channel **831** splits to form flow channels **832** and **833**. Flow channel **834** splits to form flow channels **835** and **836**. Flow channels **833** and **836** merge to form flow channel **837**, flow channels **832** and **835** merge to form flow channel **838**. Flow diverter **820** is disposed adjacent to flow channels **831**, **832**, **833**, **834**, **835**, **836**, **837**, and **838**, and has rod **822**, driver **824**, and flow control elements **825**, **826**, **827**, and **828** for diverting liquid flow.

[0145] FIG. 11b is a top view of reciprocating flow controller **810** in its first position. Driver **824** is set so that flow control elements **825** and **828** prevent flow of liquid through channels **833** and **835**, respectively, while flow control elements **826** and **827** allow flow through channels **836** and **832**, respectively. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **810** through flow channel **831**. Liquid flows through flow channel **832**, and into flow channel **838**. The liquid exits reciprocating flow controller **810** through flow channel **838**, such as liquid in tube **232** of FIG. 1. Returning liquid, such as liquid in tube **234** of FIG. 1, reenters reciprocating flow controller **810** through liquid channel **837**. Liquid flows through flow channel **836**, and into flow channel **834**, exiting reciprocating flow controller **810** through flow channel **834**, such as liquid in tube **216** of FIG. 1.

[0146] FIG. 11c is a top view of reciprocating flow controller **810** in its second position. Driver **824** is set so that flow control elements **826** and **827** prevent flow of liquid through channels **836** and **832**, respectively, while flow control elements **828** and **825** allow flow through channels **833** and **835**, respectively. In this position, incoming liquid, such as liquid in tube **212** of FIG. 1, enters reciprocating flow controller **810** through flow channel **831**. Liquid flows through flow channel **833**, and into flow channel **837**. The liquid exits reciprocating flow controller **810** through flow channel **837**, such as liquid in tube **234** of FIG. 1. Returning liquid, such as liquid in tube **232** of FIG. 1, reenters reciprocating flow controller **810** through liquid channel **838**. Liquid flows through flow channel **835**, and into flow channel **834**, exiting reciprocating flow controller **810** through flow channel **834**, such as liquid in tube **216** of FIG. 1.

[0147] Reciprocation of cleaning liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **810** between its first and second positions.

[0148] FIG. 4 is a schematic drawing of another alternative embodiment of a system utilizing devices according to the present invention. As shown, system **10** includes means for directing fluid onto a plurality of surfaces of an oral cavity, in this case shown as application tray **100**, and contained within housing **12**, piston pump **20** with piston **22** engaged with a location sensor **24**, logic circuit **30**, energy supply **32**, liquid supply reservoir **40**, liquid retention reservoir **42**, tubes **52**, **54**, **56**, **58**, liquid flow valves **62**, **64**, **66**, **68**, and pressure transducers **72**, **74**.

[0149] Housing **12** is capable of holding necessary components and is a means for holding necessary connectors. In embodiments where system **10** is sized to be hand-held, housing **12** mates with an electrical charging base station, both mechanically and electrically.

[0150] In the embodiment shown, pump **20** is shown in the form of a double acting piston pump, though it is conceived that a pair of single acting pumps, or other pump equivalents can be used. When the pump is a double acting piston pump, the pump includes piston **22**, first chamber **26**, and second chamber **28**. Piston **22** is engaged with a location sensor **24**. Pressure transducers **72**, **74** measure the pressure in first chamber **26** and second chamber **28**, respectively.

[0151] Liquid supply reservoir **40** and liquid retention reservoir **42** may be made of glass, plastic, or metal. Supply reservoir **40** may be integral to housing **12** and refillable. In some embodiments, supply chamber **40** may be a replaceable solution supply, detachably connected to housing **12**. Retention reservoir **42** is used to store spent solution at the end of the cycle, e.g. cleaning cycle. Retention reservoir **42** also may include a port or other means, not shown, for discharging spent solution.

[0152] As will be discussed below, tubes **52**, **54**, **56**, **58**, and liquid flow valves **62**, **64**, **66**, **68** connect pump **20**, liquid supply chamber **40**, liquid retention reservoir **42**, and application tray **100**.

[0153] In some embodiments, supply reservoir **40** and/or tubes **52**, **54**, may include a heat source to pre-warm liquid prior to direction into application tray **100** for application to plurality of surfaces in the oral cavity. The temperature should be maintained within a range effective to provide comfort to the user during use.

[0154] Energy supply **32** could be electrical, or in the form of replaceable or rechargeable batteries.

[0155] Application tray **100** could be integral with, or detachably connected to housing **12** by way of tubes **54**, **56** and other attachment means (not shown). It could be one or two sided with internally, easily cleanable filters for trapping food particles. Furthermore, when applied to teeth, tray **100** will form an effective fit or seal against the gums, and includes means to direct liquid against surfaces of the oral cavity.

[0156] In use, liquid in supply reservoir **40** flows through first tube **52** to first chamber **26** of pump **20**. Liquid flow through first tube **52** is controlled by first valve **62**. From first chamber **26** of pump **20**, liquid flows through second tube **54** to application tray **100**. Second valve **64** controls the liquid flow through second tube **54**. Liquid flows from application tray **100**, through

third tube **56**, to second chamber **28** of pump **20**, and is controlled by third valve **66**. Second chamber **28** of pump **20** is connected to retention reservoir **42** by fourth tube **58**. The flow of liquid through fourth tube **58** is controlled by fourth valve **68**.

[0157] Logic circuit **30** may include a program to cause application tray **100** to be filled with liquid at the start of the cycle, a program to execute the cycle, i.e. to cause liquid to be reciprocated about the plurality of surfaces of the oral cavity, e.g. teeth and gingival area, thereby providing the beneficial effect, e.g. cleaning the teeth, a program to empty application tray **100** at the end of the cycle, and a self-cleaning cycle to clean the system between uses, or at pre-set or automatic cleaning times. Logic circuit **30** includes means to detect liquid leakage, as well as means to make-up for leakage so as to maintain a relatively constant volume of liquid during the cycle. In the embodiment shown in FIG. 4, the means to detect liquid leakage uses pressure transducers **72**, **74** located in first chamber **26** and second chamber **28**, respectively.

[0158] Though not shown, a face panel with a series of switches and indicator lights may also be incorporated into system **10**. Switches may include, but are not limited to, on/off, fill application tray **100**, run the reciprocation program, empty system **10**, and clean system **10**. Indicator, or display, lights include, but are not limited to power on, charging, reciprocation program running, system emptying, cleaning results or feedback and self-cleaning cycle in operation. In embodiments where cleaning solution is pre-warmed prior to direction into application tray **100**, a display light could be used to indicate that the liquid is at the proper temperature for use.

[0159] One method of using system **10** to clean teeth is as follows. In the first step, the user positions application tray **100** in the oral cavity about the teeth and gingival area. The user applies pressure by closing down on tray **100**, thereby achieving an effective seal between gums, teeth and tray **100**. The user pushes a start button initiating loading of cleaning solution into the space between the surface of tray **100** and the teeth to be cleaned. Logic circuit **30** controls the cleaning process as follows:

1. First valve **62** opens, second valve **64** closes, piston **22** moves to its left most position drawing liquid from supply reservoir **40** through first tube **52** into first chamber **26** of pump **20**.

2. First valve **62** closes, while second **64**, third **66**, and fourth **68** valves open. Piston **22** moves to its right most position, forcing liquid through second tube **54** to application tray **100**.
3. To appropriately charge the system, steps 1 and 2 are repeated, pumping liquid as above until a pre-determined pressure is detected in both pressure transducers **72**, **74**, indicating that an appropriate amount of liquid is contained within chambers **26** and **28**. Chambers **26** and **28** may be completely or partially filled, so long as the amount is effective to maintain reciprocating movement of the liquid through the application tray and about the plurality of surfaces of the oral cavity during use.
4. First valve **62** and fourth valve **68** close, while second valve **64** and third valve **66** remain open.
5. Piston **22** cycles from its left to right positions and back, forcing liquid to be cycled back and forth across the surfaces, e.g. teeth, in application tray **100**.
6. If a loss of pressure is detected by either pressure transducer **72**, or **74**, steps 1 to 3 are repeated to maintain the appropriate volume of liquid in first chamber **26** and second chamber **28** of pump **20**.
7. The process continues to run until the time required for achieving the beneficial effect, e.g. cleaning, has expired, the cycles are complete, or the system has cycled a number of times without pressure building-up, indicating that the liquid supply has been exhausted.

[0160] In embodiments where liquid is pre-warmed prior to entry into application tray **100**, a temperature sensor is incorporated in the circuit to warn the user that the solution is too cold to use, and a method of heating the solution is provided.

[0161] In some embodiments, multiple liquid supplies may be utilized as shown in FIG. 5. The figure shows only the liquid supply portion of system **10** (FIG. 4). Logic circuit **30** controls the process as follows:

1. First valve **62a** opens, valves **62b**, **62c**, and second valve **64** close, piston **22** moves to its left most position drawing liquid from supply reservoir **40a** through tubes **52a** and **52** into first chamber **26** of pump **20**.
2. First valve **62a** closes, while second **64**, third **66**, and fourth **68** valves open. Piston **22** moves to its right most position forcing liquid through second tube **54** to application tray **100**.
3. To fully charge the system, steps 1 and 2 are repeated, pumping liquid until pressure is detected in both pressure transducers **72**, **74**.

4. First valve **62** and fourth valve **68** close, while second valve **64** and third valve **66** remain open.
5. Piston **22** cycles from its left to right most positions, forcing liquid to be cycled back and forth across the surfaces of the oral cavity in application tray **100**.
6. If pressure is lost in either pressure transducer **72**, **74**, steps 1 to 3 are repeated, recharging the system when pressure is built back up in first chamber **26** and second chamber **28** of pump **20**.
7. The process runs until the time is up, the cycles are complete, or the system has cycled a number of times without pressure building up indicating that the liquid has been used up.
8. First valve **62a** closes, valve **62b** opens, valve **62c** remains closed, and steps 1 to 7 are repeated with liquid in supply reservoir **40b**.
9. First valve **62a** remains closed, valve **62b** closes, valve **62c** opens, and steps 1 to 7 are repeated with cleaning solution in liquid supply reservoir **40c**.

[0162] It is important to note that this sequence can be repeated indefinitely with additional supplies of liquid in the respective supply reservoirs. In addition, the final liquid supply reservoir may contain water or other cleaning liquids and the system may be purged for cleaning.

[0163] The oral hygiene system may be comprised of several major components including, but not limited to, a base station, a hand piece for containing means for providing reciprocation of liquid about the plurality of surfaces within the oral cavity, and the application tray, or mouthpiece. The system is suitable for in-home use and adapted to direct liquid onto a plurality of surfaces of a tooth simultaneously. The device cleans teeth and removes plaque using cleaning solution that is reciprocated back and forth creating a cleaning cycle and minimizing cleaning solution used. The device could be hand held, or may be in the form of a table or counter-top device.

[0164] The base station will charge a rechargeable battery in the hand piece, hold liquid reservoirs, house diagnostic components, provide feedback to the user, and potentially clean the mouthpiece.

[0165] The hand piece will have a powered pump that will deliver liquid from the reservoir to the mouthpiece. The direction of flow may be reciprocated with liquid control valving, by a specialized pump (reversing its direction, etc), reversible check valves, or other similar means. The cycle time and flow velocity for each stage of the cycle will be variable and in some embodiments, be customized to each individual user. The hand piece will perform a filling

process, and a cleaning and/or purging process. The hand piece and/or base station may provide feedback to the user for each stage of the process and potentially report diagnostic information.

[0166] The hand piece will be aesthetically pleasing and have a grip/feel comfortable for the user's hand. The weight and balance will be well suited to comfortable and efficient use while giving a high quality feel. Finger grips and/or touch points will be appropriately located for comfort, grip, feel, and assistance in proper orientation and grip location of the hand piece. The base station will also be aesthetically pleasing and allow the hand piece to easily and securely dock into position. The base station may or may not lock the hand piece into position once it's docked.

[0167] The third major component of the apparatus is the application tray, or mouthpiece.

[0168] FIG. 12 is a top perspective view of a first embodiment of a device according to the present invention, e.g. application tray **100**. FIG. 13 is a bottom perspective view of the application tray **100** of FIG. 12. The figures show application tray **100** with outer front wall **112**, outer back wall **114**, inner front wall **116**, inner back wall **118**, and base membrane, e.g. bite plate, **156**. Inner front wall jet slots **132** are located on inner front wall **116**, while inner back wall jet slots **134** are located on inner back wall **118**. The inner front wall jet slots **132** and inner back wall jet slots **134** shown in FIGs. 12 and 13 are only one embodiment of jet slot configuration. First port **142** and second port **144** enter application tray **100** through outer front wall **112**.

[0169] FIGs. 12 and 13 depict an embodiment of an application tray **100** in which the user's top and bottom teeth and/or gingival area are substantially simultaneously contacted with liquid to provide the desired beneficial effect. It should be understood that in other embodiments, application tray **100** may be designed to clean and/or treat only the top or bottom teeth and/or gingival area of the user.

[0170] FIGs. 14 and 15 are vertical and horizontal, respectively, sectional views of the application tray **100** of FIG. 12. The figures show first manifold **146**, defined as the space bordered by outer front wall **112** and inner front wall **116**. Second manifold **148** is defined as the space bordered by outer back wall **114** and inner back wall **118**. The liquid-contacting chamber (LCC) **154** is defined by inner front wall **116**, inner back wall **118**, and base membrane **156**.

[0171] In one embodiment of an operation, liquid enters first manifold **146** through first port **142** by pressure and then enters LCC **154** through inner front wall jet slots **132**. A vacuum is pulled on second port **144** to pull the liquid through inner back wall jet slots **134**, into second manifold **148** and finally into second port **144**. In this embodiment, jets of liquid are first directed onto the front surfaces of the teeth and/or gingival area from one side of the LCC **154**, directed through, between, and around the surfaces of the teeth and/or gingival area from the other side of LCC **154** into the second manifold to provide controlled interdental, gumline, surface and /or gingival area cleaning or treatment. Next, the flow in the manifolds is reversed. Cleaning liquid enters second manifold **148** through second port **144** by pressure and then enters LCC **154** through inner back wall jet slots **134**. A vacuum is pulled on first port **142** to pull the liquid through inner front wall jet slots **132**, into first manifold **146** and finally into first port **142**. In the second portion of this embodiment, jets of liquid are directed onto the back surfaces of the teeth and/or gingival area, and directed through, between, and around the surfaces of the teeth and/or gingival area. The alternating of pressure/vacuum through a number of cycles creates a turbulent, repeatable and reversible flow to provide reciprocation of liquid about the plurality of surfaces of the oral cavity to substantially simultaneously contact the surfaces of the oral cavity with liquid, thereby providing the desired beneficial effect.

[0172] In another embodiment it may be preferable to deliver the liquid through one or both manifolds simultaneously, flooding LCC **154**, submerging the teeth for a period of time and then evacuating LCC **154** after a set period of time through one or both manifolds. Here, cleaning or treating liquid simultaneously enters first manifold **146** through first port **142**, and second manifold **148** through second port **144** by pressure and then enters LCC **154** simultaneously through inner front wall jet slots **132** and inner back wall jet slots **134**. To evacuate LCC **154**, a vacuum is simultaneously pulled on first manifold **146** through first port **142**, and second manifold **148** through second port **144**. Cleaning or treatment liquid is pulled through inner front wall jet slots **132** and inner back wall jet slots **134**, into first manifold **146** and second manifold **148**.

[0173] It is also possible to deliver different liquid compositions to first manifold **146** and second manifold **148**. The different liquid compositions could then combine in the LCC for improved cleaning efficacy or treatment effects.

[0174] FIG. 16 is a top, rear perspective view of a second embodiment of an application tray **1100** according to the present invention. FIG. 17 is a top, front perspective view of the application tray **1100** of FIG. 16, while FIG. 18 is a top view of the application tray of FIG. 16.

The figures show application tray **1100** with top piece **1102**, bottom piece **1104**, first port **1142**, second port **1144**, and support plate **1108** fixedly attached to the front of said application tray. First port **1142** and second port **1144** enter application tray **1100** and extend through support plate **1108**.

[0175] Optional quick disconnect structures, e.g. barbs, **1110** are attached to support plate **1108**, allowing application tray **1100** to be quickly and easily attached to and then disconnected from means for providing liquid to the application tray, such as may be contained in housing **12** of device **10**, as shown in FIG. 4. The housing would include structure effective to receive such quick disconnect barbs, or similar quick disconnect structure, in attachable engagement, to detachably connect the application tray to the housing. The quick disconnect option could be used to replace used or worn application trays, or to change application trays for different users. In some embodiments, a single user may change application trays to change the flow characteristics for different options, such as number of cleaning nozzles, nozzle velocity, spray pattern, and locations, coverage area, etc.

[0176] FIGs. 16 to 19 depict an embodiment of an application tray **1100** in which the user's top and bottom teeth and/or gingival area are substantially simultaneously contacted with liquid. It should be understood that in other embodiments, application tray **1100** may be designed to contact only the top or bottom teeth or gingival area of the user with liquid.

[0177] Top piece **1102** has front liquid lumens **1102a**, **1102b**, **1102c**, and **1102d**, back liquid lumens **1102e**, **1102f**, and **1102g**, first manifold **1146**, second manifold **1148**, base membrane **1156**, and back gum-sealing membrane **1158**. Front liquid lumens **1102a**, **1102b**, **1102c**, and **1102d** are all connected by first manifold **1146**, and optionally (as shown on FIGs. 16 to 19), connected to each other along all, or part of, their length. Likewise, back liquid lumens **1102e**, **1102f**, and **1102g**, are all connected by second manifold **1148**, and optionally, connected to each other along all, or part of, their length.

[0178] Bottom piece **1104**, may be a mirror image of top piece **1102**, and has front liquid lumens **1104a**, **1104b**, **1104c**, and **1104d**, back liquid lumens **1104e**, **1104f**, and **1104g**, first manifold **1146**, second manifold **1148**, base membrane **1156**, and back gum-sealing membrane **1158**. Front liquid lumens **1104a**, **1104b**, **1104c**, and **1104d** are all connected by first manifold **1146**, and optionally (as shown on FIGs. 16 to 19), connected to each other along all, or part of, their length. Likewise, back liquid lumens **1104e**, **1104f**, and **1104g**, are all

connected by second manifold **1148**, and optionally, connected to each other along all, or part of, their length.

[0179] Though FIGs. 16 and 17 show top piece **1102** with four front liquid lumens (**1102a**, **1102b**, **1102c**, and **1102d**) and three back liquid lumens (**1102e**, **1102f**, and **1102g**), top piece **1102** may also be formed with two, three, five, six, or even seven front or back liquid lumens. Likewise, bottom piece **1104** is shown with four front liquid lumens (**1104a**, **1104b**, **1104c**, and **1104d**) and three back liquid lumens (**1104e**, **1104f**, and **1104g**), bottom piece **1104** may also be formed with two, three, five, six, or even seven front or back liquid lumens.

[0180] The liquid-contacting chamber ((LCC) **1154a**, mentioned above, is located in top piece **1102**, defined by front liquid lumens (**1102a**, **1102b**, **1102c**, and **1102d**), back liquid lumens (**1102e**, **1102f**, and **1102g**), base membrane **1156**, and back gum-sealing membrane **1158**. Though not shown, bottom piece **1104** also has a LCC **1154b**, defined by front liquid lumens (**1104a**, **1104b**, **1104c**, and **1104d**), back liquid lumens (**1104e**, **1104f**, and **1104g**), base membrane **1156**, and back gum-sealing membrane **1158**.

[0181] The multi-lumen design provides bidirectional or dedicated lumens for flow and vacuum that are self-reinforcing and therefore do not collapse under vacuum or rupture under pressure while in use, maximizing the structural integrity, while minimizing the size of the overall application tray **1100** for user comfort during insertion, in-use, and upon removal. This decreased size also serves to provide an enhanced effective seal of the application tray in the oral cavity.

[0182] If the multiple lumens (**1102a**, **1102b**, **1102c**, **1102d**, **1102e**, **1102f**, **1102g**, **1104a**, **1104b**, **1104c**, **1104d**, **1104e**, **1104f**, and **1104g**) are connected as described above, they form a lumen hinge sections (**1103** on FIG. 17). This may result in the multi-lumen design providing conformance in the X, Y and Z directions, due to the flexibility of lumen hinge sections **1103** between each lumen. This design allows effective and feasible conformance to a variety of different users teeth and gum topography, providing the effective gum sealing without irritating the gums and allowing dynamic positioning of the liquid cleaning jets around each of the teeth to obtain proximal and interdental cleaning action. The multiple lumens are also attached to the first manifold **1146** and second manifold **1148**. This creates a secondary flexible joint providing two additional degrees of motion for the adjusting to different bite architectures that may be encountered.

[0183] The back gum-sealing membrane **1158** proves a flexible and universal sealing mechanism to minimize leakage into the oral cavity while redirecting flow onto and around teeth, to maximize treatment/cleaning area to get to hard-to-reach-places (HTRP). The membrane can provide an elastic function across the lumen longitudinal axis to form around the teeth and gums.

[0184] Base membrane **1156** provides the flexibility required for effective fit or sealing within the oral cavity and allowing redirection and flow of jets back towards the teeth and/or gingival surfaces.

[0185] Optionally, application tray **1100** could also include gum-sealing component if required, which could be attached to the front liquid lumens **1102a**, **1102b**, **1104a**, and **1104b**, and back liquid lumens **1102e** and **1104e** (member furthest from teeth).

[0186] Optionally, frictional elements, such as filament tufts, could also be placed or secured through any of the lumen hinge sections **1103** without significantly increasing the size of application tray **1100**, or impacting user comfort or liquid flow in the application tray **1100**.

[0187] Inner front wall jet slots **1132** are located on inner front wall of top piece **1102** and bottom piece **1104**, while inner back wall jet slots **1134** are located on inner back wall of top piece **1102** and bottom piece **1104**. Though only one inner front wall jet slot **1132** and inner back wall jet slot **1134** are shown in FIGs. 13 to 16, the number, shape and size of inner front wall jet slots **1132** and inner back wall jet slots **1134** affect the cleaning of the teeth and gums, and can be designed to direct jets of cleaning liquid in a variety of spray patterns. The inner front wall jet slots **1132** and inner back wall jet slots **1134** shown in FIGs. 16 to 19 are only one embodiment of jet slot configuration.

[0188] FIGs. 16 and 17 depict an embodiment of an application tray **1100** in which surfaces of the users top and bottom teeth and/or gingival area are substantially simultaneously contacted by liquid to provide the desired beneficial effect. It should be understood that, in other embodiments, application tray **1100** may be designed to contact only the top or bottom teeth and/or gingival area of the user.

[0189] FIG. 19 is a cut-away view of the application tray **1100** of FIG. 16. The figure shows first manifold **1146** and second manifold **1148**. In one embodiment of a cleaning operation, cleaning liquid is pumped through first port **1142**, and enters first manifold **1146** through first

flow diverter **1143**. Liquid enters front liquid lumens **1102a**, **1102b**, **1102c**, **1102d**, **1104a**, **1104b**, **1104c** and **1104d** through front liquid lumen ports **1147**. The cleaning liquid then enters LCCs **1154a** and **1154b** through inner front wall jet slots **1132**. A vacuum is pulled on second port **1144** to pull the cleaning liquid through inner back wall jet slots **1134**, into back liquid lumens **1102e**, **1102f**, **1102g**, **1104e**, **1104f**, and **1104g**. The liquid enters second manifold **1148** through back liquid lumen ports **1149**, then through second flow diverter **1145**, and finally into second port **1144**.

[0190] In this embodiment, jets of cleaning liquid are first directed from first manifold **1146** to the front surfaces of the teeth and/or gingival area from one side of the LCCs, directed through, between, and around the surfaces of the teeth and/or gingival area from the other side of the LCCs into the second manifold **1148** to provide controlled interdental, gumline, surface and /or gingival area cleaning or treatment.

[0191] Next, the flow in the manifolds is reversed. Cleaning liquid is pumped through second port **1144**, and enters second manifold **1148** through second flow diverter **1145**. Liquid enters back liquid lumens **1102e**, **1102f**, **1102g**, **1104e**, **1104f**, and **1104g** through back liquid lumen ports **1149**. The cleaning liquid then enters LCCs **1154a** and **1154b** through inner back wall jet slots **1134**. A vacuum is pulled on first port **1142** to pull the cleaning liquid through inner front wall jet slots **1132**, into front liquid lumens **1102a**, **1102b**, **1102c**, **1102d**, **1104a**, **1104b**, **1104c** and **1104d**. The liquid enters first manifold **1146** through front liquid lumen ports **1147**, then through first flow diverter **1143**, and finally into first port **1144**.

[0192] In the second portion of this embodiment, jets of cleaning liquid are directed onto the back surfaces of the teeth and/or gingival area, and directed through, between, and around surfaces of the teeth and/or gingival area. The alternating of pressure/vacuum through a number of cycles creates a turbulent, repeatable and reversible flow to provide reciprocation of liquid about the plurality of surfaces of the oral cavity to substantially simultaneously contact the surfaces of the oral cavity with liquid, thereby providing the desired beneficial effect.

[0193] In another embodiment it may be preferable to deliver the liquid through one or both manifolds simultaneously, flooding LLCs **1154a** and **1154b**, submerging the teeth for a period of time and then evacuating the LCCs after a set period of time through one or both manifolds. Here, cleaning or treating liquid is simultaneously pumped through first port **1142** into first manifold **1146** via first flow diverter **1143**, and through second port **1144** into second manifold **1148** via second flow diverter **1145**. Liquid then simultaneously enters front liquid lumens

1102a, 1102b, 1102c, 1102d, 1104a, 1104b, 1104c and 1104d through front liquid lumen ports **1147**, and back liquid lumens **1102e, 1102f, 1102g, 1104e, 1104f, and 1104g** through back liquid lumen ports **1149**. The cleaning liquid then enters LCCs **1154a** and **1154b** through inner front wall jet slots **1132** and inner back wall jet slots **1134**. To evacuate the LCCs, a vacuum is simultaneously pulled on first manifold **1146** through first port **1142**, and second manifold **1148** through second port **1144**. Cleaning or treatment liquid is pulled through inner front wall jet slots **1132** and inner back wall jet slots **1134**, into first manifold **146** and second manifold **148**.

[0194] It is also possible to deliver different liquid compositions to first manifold **1146** and second manifold **1148**. The different liquid compositions would then combine in the LCC for improved cleaning efficacy or treatment effects. In the dual manifold design it may be preferable to supply each manifold from a separate liquid supply reservoir, such as in a dual action piston pump configuration, where one supply line connects to supply first manifold **1146** and the other piston supply line provides and removes liquid from second manifold **1148**, e.g. when one manifold is being supplied with liquid the second manifold is removing liquid, and vice versa.

[0195] In other embodiments, valves can be placed at front liquid lumen ports **1147** of front liquid lumens **1102a, 1102b, 1102c, 1102d, 1104a, 1104b, 1104c and 1104d**, or at back liquid lumen ports **1149** of back liquid lumens **1102e, 1102f, 1102g, 1104e, 1104f, and 1104g** to provide improved function by allowing lumens to engage at different times (at different points in the cleaning/treatment cycle), at pulsed intervals. As an example, in one embodiment, not all lumens engage in the liquid pumping/vacuum function. Here, front liquid lumens **1102a** and **1104a**, and back liquid lumens **1102e** and **1104e**, which primarily engage the gums, only engage in the liquid vacuum function. This would help prevent liquid from leaking into the oral cavity. Valving also allows for variable flow, allowing a decreased resistance to the liquid vacuum function, or allowing increased pumping, and therefore liquid velocity, during liquid delivery.

[0196] In still other embodiments, individual inner front wall jet slots **1132** or inner back wall jet slots **1134** may have integrated one-way valves, such as duckbill valves or umbrella valves, to allow flow only in one direction out of those particular jets. This may be effective to increase vacuum relative to pressure/delivery in the LCC.

[0197] In some embodiments, the motion of the frictional elements discussed above, relative to the teeth, could be applied by a single or combination of mechanisms including, by not limited to, the liquid (via the jet slots or via turbulence of flow); movement of the membrane via the pulsing of the flexible application tray **1100**; an external vibrational mechanism to vibrate the frictional elements; linear and or rotational movement of the application tray **1100** around the teeth through user jaw motion or external driving means.

[0198] In other embodiments, a conformable substance, such as gel, may be disposed near the back gum-sealing membrane **1158**, allowing application tray **1100** to comfortably fit against the back of the mouth. Alternatively, the end of application tray **1100** may have a mechanism or attachment to extend or decrease the length of the mouthpiece to the proper length for each individual user, providing a semi-custom fit.

[0199] Manufacturing of the multi-lumen design is feasible utilizing existing available manufacturing and assembly processes such as extrusion, injection, vacuum, blow, or compression molding. Other feasible techniques include rapid prototyping techniques such as 3D printing and other additive techniques, as well as subtractive techniques.

[0200] The application tray may be custom manufactured for each individual user, or customizable by the individual user prior to use. For custom manufacture of the application tray, vacuum form molds can be created directly or indirectly from user teeth and gingival impressions, which create a model of the teeth which can then be modified to create required clearances and flow channels. These vacuum form molds can be created at low cost utilizing CAD and rapid prototyping processes.

[0201] One manufacturing method is to create individual component shells through vacuum forming. Low cost methods allow vacuuming forming of very thin wall structures. The component geometry is designed to provide the interlocking features and structural geometry to allow minimization of the size of the application tray. When assembled, the manufactured components form the necessary manifolds and flow structure (bidirectional and/or dedicated manifolds) to provide the required performance characteristics for treating/cleaning the teeth.

[0202] Customized mouthpieces are based on the user's teeth geometry, therefore creating a consistent distance between the mouthpiece and teeth may provide a more consistent cleaning/treating experience. The materials for each of the two-piece shell may be different,

therefore allowing for softer material (on the inside shell) where it contacts teeth/gums and harder material on the outside shell to maintain rigidity and the overall shape.

[0203] For customizable application trays, tray pre-forms (similar to sport mouth guards or teeth grinding appliances) containing pre-manufactured manifolds, nozzles and channels are mass manufactured. The tray pre-forms can be created through a variety of known manufacturing techniques including, but not limited to, blow molding, vacuum forming, injection and/or compression molding. The material used in the pre-form would be a low temperature deformable plastic material. The pre-form would be used in conjunction with required spacers to be applied over the teeth to provide required clearance, cleaning and/or treatment performance. Once the clearance components are applied to the teeth, the pre-form would be heated via microwave or by placing in boiling water so as to be pliable. The pliable pre-form would be applied onto the user's teeth and gingival area to create the customized application tray.

[0204] The application tray can be integrated with stressing features to allow elastic conformance to maximize positioning, comfort and performance during application and in use. For example, spring-like elements such as shins, clips and elastic bands may provide fitting over and against gums.

[0205] Materials for the MP lumen could range from lower durometer flexible materials (25 shore A) to harder materials more rigid materials (90 shore A), preferably being between 40 and 70 shore A.

[0206] Materials could be silicone, thermoplastic elastomer (TPE), polypropylene (PP), polyethylene (PE), polyethylene terephthalate (PET), ethylene vinyl acetate (EVA), polyurethane (PU), or multi-component (combination of materials and hardness) to achieve desired design and performance attributes.

[0207] The jet openings or slots could be made through a secondary operation such as drilling or punching, or formed during molding. Alternatively, the jet openings or slots could be inserted into the application tray to provide increased wear and or different jet performance characteristics, and could be combined with frictional cleaning elements or other components to enhance the cleaning and/or treatment affect.

[0208] FIGs. 20 to 23 depict an embodiment of an application tray **1200** in which only the user's top or bottom teeth and gingival area are contacted with liquid. It should be understood that in other embodiments, application tray **1200** may be designed to substantially simultaneously contact both the top and bottom teeth and gingival area of the user, as depicted elsewhere herein.

[0209] FIG. 20 is a top front perspective view of a third embodiment of an application tray **1200** according to the present invention. FIG. 21 is a top back view of the embodiment of the application tray **1200** of FIG. 20, while FIG. 22 is a bottom back view of the application tray **1200** of FIG. 20. The figures show application tray **1200** with outer front wall **1212**, outer back wall **1214**, inner front wall **1216**, and inner back wall **1218**. Inner front wall jet slots **1232** are located on inner front wall **1216**, while inner back wall jet slots **1234** are located on inner back wall **1218**. First port **1244** and second port **1242** enter application tray **1200** through outer front wall **1212**.

[0210] The number and location of inner front wall jet slot **1232** and inner back wall jet slot **1234** as shown in FIGs. 20 to 23 is exemplary and is not intended to limit the scope of the application tray. The actual number, shape and size of inner front wall jet slots **1232** and inner back wall jet slots **1234** affect the cleaning of the teeth and gums, and can be selected or designed to direct jets of cleaning liquid in a variety of spray patterns. The inner front wall jet slots **1232** and inner back wall jet slots **1234** shown in FIGs. 20 to 22 are only one embodiment of jet slot configuration.

[0211] FIG. 23 is a vertical sectional view of the application tray **1200** of FIG. 20. The figures show first manifold **1246**, defined as the space bordered by outer front wall **1212** and inner front wall **1216**. Second manifold **1248** is defined as the space bordered by outer back wall **1214** and inner back wall **1218**. The liquid contact chamber (LCC) **1254** is defined by inner front wall **1216**, inner back wall **1218** and inner base wall **1250**.

[0212] In one embodiment of a cleaning operation, cleaning liquid enters first manifold **1246** through first port **1244** by pressure and then enters LCC **1254** through inner front wall jet slots **1232**. A vacuum is pulled on second port **1242** to pull the cleaning liquid through inner back wall jet slots **1234**, into second manifold **1248** and finally into second port **1242**. In this embodiment, jets of cleaning liquid are first directed onto the front side of the teeth from one side of the LCC, directed through, between, and around the teeth from the other side of the LCC into the second manifold to provide controlled interdental, gumline, surface and /or

gingival area cleaning. Next, the flow in the manifolds is reversed. Cleaning liquid enters second manifold **1248** through second port **1242** by pressure and then enters LCC **1254** through inner back wall jet slots **1234**. A vacuum is pulled on first port **1244** to pull the cleaning liquid through inner front wall jet slots **1232**, into first manifold **1246** and finally into first port **1244**. In the second portion of this embodiment, jets of cleaning liquid are directed onto the back side of the teeth, and directed through, between, and around the teeth and/or gingival area. The alternating of pressure/vacuum through a number of cycles creates a turbulent, repeatable and reversible flow, thereby providing reciprocation of liquid over and about the surfaces of the oral cavity.

[0213] It is also possible to deliver different liquid compositions to first manifold **1246** and second manifold **1248**. The different liquid compositions would then combine in the LCC for improved cleaning efficacy. In the dual manifold design it may be preferable to supply each manifold from a separate chamber, such as in a dual action piston pump configuration, where one supply line connects and to supply first manifold **1246** and the other piston supply line provides and removes from second manifold **1248** (when one manifold is being supplied the second manifold is removing and vice versa).

[0214] An embodiment of a hand-held device used with devices according to the present invention is shown in FIGs. 24a to 24e. FIG. 24a is an exploded view of a hand piece **3000** that pumps liquid to, and pulls liquid from, the application tray, thus providing reciprocation of the liquid to and from the application tray. In this embodiment, device **3000** is designed in a modular fashion, with a pumping section, a vacuum section, a reciprocating section, and pumping and driving sections. Modular construction allows for easier design for manufacturing (DFM), with easy assembly and repair. The embodiment is also designed to minimize the size of the device as well as the amount of liquid used in operation.

[0215] Device **3000** includes outlet pipes **3010a** and **3010b**, reciprocating flow controller **710**, inlet disk top section **3050**, inlet disk bottom section **3090**, delivery cylinder sleeve **3110** with bubble-break plate **3115** and delivery cylinder filling tube **3112**, separator plates **3210**, **3310**, vacuum end disks **3250**, **3290**, vacuum piston **3270**, vacuum cylinder sleeve **3410**, piston rod **3460**, indexing shaft **3470**, and diverter drive gear **3472**.

[0216] An exploded view of pumping section of device **3000** is shown on FIG. 24b. The figure shows outlet pipes **3010a**, **3010b** attached to cap **720** of reciprocating flow controller **710**. Flow diverter disk **730**, with position adjuster **732** in the form of a gear, is disposed in cap

720 and sits on base **740**. O-ring **736** is between flow diverter disk **730** and base **740**. Base ports **742** and **744** pass through base **740**. Panel **735** for diverting liquid flow is disposed in flow diverter disk **730**. Inlet disk top section **3050** has inlet disk top section ports **3051**, **3052**, **3053**, and **3054**, and is separated from base **740** by sealing gasket **3030**. Inlet disk bottom section **3090** has inlet disk bottom section ports **3091**, **3092**, **3095**, **3096**. Dual flap valve **3070** is between inlet disk top section **3050** and inlet disk bottom section **3090**, with the two flaps of dual flap valve **3070** above inlet disk bottom section ports **3091** and **3092** and below inlet disk top section ports **3052** and **3053**. Inlet disk bottom section port **3091** includes a one-way valve **3093**, allowing liquid to flow from inlet disk top section port **3052** to inlet disk bottom section port **3091** through dual flap valve **3070**. Inlet disk bottom section port **3092** includes a one-way valve **3094**, allowing liquid to flow from inlet disk bottom section port **3092** to inlet disk top section port **3053** through dual flap valve **3070**. Inlet disk bottom section **3090** is disposed on top of delivery cylinder sleeve **3110**. Delivery is disposed along delivery cylinder sleeve **3110**, while delivery piston **3130** is disposed in the volume defined by delivery cylinder sleeve **3110**. Bubble-break plate **3115** is disposed about cylinder sleeve **3110**. Delivery volume **3114** is the volume defined by delivery cylinder sleeve **3110** minus the volume of delivery piston **3130**.

[0217] FIG. 24c is an exploded view of vacuum section of device **3000**. The figure shows separator plate **3210**, with separator plate ports **3212** and **3214**, disposed on top of vacuum end disk **3250**. Vacuum end disk **3250** has vacuum end disk ports **3251** and **3252**. Flap valves **3230a** and **3230b** are between separator plate **3210** and vacuum end disks **3250**. Flap valves **3230a** and **3230b** are above vacuum end disk ports **3251** and **3252** and below separator plate ports **3212** and **3214**. Vacuum end disk port **3251** includes a one-way valve **3253**, allowing liquid to flow from vacuum end disk port **3251** to separator plate port **3214** through flap valve **3230a**. Vacuum end disk port **3252** includes a one-way valve **3254**, allowing liquid to flow from separator plate port **3212** to vacuum end disk port **3252** through flap valve **3230b**. Vacuum piston **3270**, disposed under vacuum end disks **3250**, has piston rod hole **3272** through which piston rod **3460** passes. Beneath vacuum piston **3270** is vacuum end disk **3290**, disposed on top of separator plate **3310**. Vacuum end disk **3290** has vacuum end disk ports **3291** and **3292**. Separator plate **3310** has separator plate ports **3312** and **3314**. Flap valves **3230c** and **3230d** are between vacuum end disk **3290** and separator plate **3310**, above vacuum end disk ports **3291** and **3292** and below separator plate ports **3312** and **3314**. Vacuum end disk port **3291** includes a one-way valve **3293**, allowing liquid to flow from vacuum end disk ports **3291** towards separator plate port **3314** through flap valve **3230c**. Vacuum end disk port **3292** includes a one-way valve **3294**, allowing liquid to flow from separator plate port **3312** to vacuum end disk port **3292** through flap valve **3230d**.

[0218] FIG. 24d is a side view of drive system of the pumping and driving sections of device **3000**. Motor **3420** drives shaft **3422**, which is linked to crankshaft arms **3430a** and **3430b**, and worm gear **3450**. Crankshaft arms **3430a** and **3430b** are linked to crankshaft link arm **3435**, which is linked to piston rod **3460**. Piston rod **3460** is attached to vacuum piston **3270** and, though not shown, delivery piston **3130**. Indexing shaft **3470** is in contact with worm gear **3450**, which is linked to diverter drive gear **3472**. When shaft **3412** spins, crankshaft arms **3430a**, **3430b** and crankshaft link arm **3435** convert the rotary motion of shaft **3422** to a linear, reciprocating motion on piston rod **3460**, such that vacuum piston **3270** and delivery piston **3130** move up and down. Simultaneously, worm gear **3450** converts the rotary motion of shaft **3422** to a rotary motion of indexing shaft **3470**. Indexing shaft **3470** rotates diverter drive gear **3472**, which is linked to position adjuster **732** in reciprocating flow controller **710**.

[0219] FIG. 24e is a cut-away view of device **3000**, showing the spatial relationships between the components in the pumping section, vacuum section, and pumping and driving sections. Cylinder volume **3412** is the volume of vacuum cylinder sleeve **3410** not occupied by the components of the pumping section, vacuum section, and pumping and driving sections, and serves as the liquid reservoir in the embodiment shown. The general operation of device **3000**, is as follows:

1. Device **3000** is sufficiently filled with cleaning liquid. The liquid initially resides in cylinder volume **3412** of vacuum cylinder sleeve **3410**.
2. The user inserts any embodiment of an application tray, for example application tray **100** or **1100**, into their mouth. Device **3000** may be activated by a sensor (pressure sensor, proximity sensor, etc.) or the device may be activated by the user. The cleaning cycle is initiated.
3. On the "down stroke" of piston rod **3460**, delivery piston **3130** pulls liquid from the bottom of cylinder volume **3412**. The liquid flows through delivery cylinder filling tube **3112**, inlet disk bottom section port **3095**, inlet disk top section port **3051**, inlet disk top section port **3052**, dual flap valve **3070**, and one-way valve **3093** in inlet disk bottom section port **3091**, and into delivery volume **3114**. It is preferred that the entry port **3116** on delivery cylinder filling tube **3112** is located at the bottom of the tube to minimize the total liquid required for cleaning/treatment and to avoid pulling air into delivery volume **3114**.
4. On the "upstroke" of piston rod **3460**, delivery piston **3130** forces the liquid through inlet disk bottom section port **3092** with one-way valve **3094**. The liquid flows through dual flap valve **3070**, through inlet disk top section port **3053**, and finally through base port **742** of reciprocating flow controller **710**.

5. Liquid flow through reciprocating flow controller **710** is described earlier using FIG. 9c and FIG. 9d. In brief, when reciprocating flow controller **710** is in its first position (FIG. 9c), incoming liquid from inlet disk top section port **3053** enters reciprocating flow controller **710** through base port **742**. The liquid exits reciprocating flow controller **710** through cap port **722**, flowing into outlet pipe **3010b**. Returning liquid, flowing in through outlet pipe **3010a**, reenters reciprocating flow controller **710** through cap port **724**. The liquid exits reciprocating flow controller **710** through base port **744**. When reciprocating flow controller **710** is in its second position (FIG. 9d), incoming liquid from inlet disk top section port **3053** enters reciprocating flow controller **710** through base port **742**. The liquid exits reciprocating flow controller **710** through cap port **724**, flowing into outlet pipe **3010a**. Returning liquid, flowing in through outlet pipe **3010b**, reenters reciprocating flow controller **710** through cap port **722**. The liquid re-exits reciprocating flow controller **710** through base port **744**. Reciprocation of cleaning liquid in application tray **100** of FIG. 1 is achieved by switching reciprocating flow controller **710** between its first and second positions. As shown in FIG. 24d, the switching of reciprocating flow controller **710** between its first and second positions is achieved by worm gear **3450**, which converts the rotary motion of shaft **3422** to a rotary motion of indexing shaft **3470**. Indexing shaft **3470** rotates diverter drive gear **3472**, which is linked to position adjuster **732** in reciprocating flow controller **710**. Though shown as continually rotating in this embodiment, it is to be understood that reciprocating flow controller **710** may be driven via separate means, such as another motor. Also, the time interval for switching reciprocating flow controller **710** between its first and second positions may, in some embodiments be between about 1 and about 100 seconds, or between about 2 and about 10 seconds, and may be varied over the course of the cleaning/treatment.
6. In the present embodiment, the vacuum section of device **3000** is effective during both the "upstroke" and "down stroke" of piston rod **3460**. Vacuum piston **3270** is dual acting, and draws liquid from application tray **100** on both the upstroke and down stroke of vacuum piston **3270**. The liquid flowing through base port **744** of reciprocating flow controller **710** flows through inlet disk top section port **3054** and continues through inlet disk bottom section port **3096**, arriving in vacuum return tube **3411**. The liquid in vacuum return tube **3411** is then drawn to vacuum volumes **3275a** or **3275b**. Vacuum volume **3275a** is the volume between vacuum end disk **3250** and vacuum piston **3270**. Vacuum volume **3275b** is the volume between vacuum end disk **3290** and vacuum piston **3270**. During the "upstroke" of piston rod **3460**, the liquid in vacuum return tube **3411** is drawn through separator plate port **3312**, and flows through flap valve **3230d**, one-way valve **3294**, and vacuum end disk port **3292**, arriving in vacuum volume **3275b**. During the "down stroke" of

piston rod **3460**, the liquid in vacuum return tube 3411 is drawn through separator plate port **3212**, and flows through flap valve **3230b**, one-way valve **3254**, and vacuum end disk port **3222**, arriving in vacuum volume **3275a**. As noted, the vacuum piston **3270** in this embodiment is dual acting, drawing liquid from application tray **100** on both the upstroke and down stroke of vacuum piston **3270**. So, while vacuum volume **3275b** is drawing in liquid from vacuum return tube 3411, the liquid in vacuum volume **3275a** is being pumped into cylinder volume **3412**. In contrast, while vacuum volume **3275a** is drawing in liquid from vacuum return tube 3411, the liquid in vacuum volume **3275b** is being pumped into cylinder volume **3412**. During the “upstroke” of piston rod **3460**, the liquid in vacuum volume **3275a** is pumped through vacuum end disk port **3251**, and flows through one-way valve **3253**, flap valve **3230a**, and separator plate port **3214**, arriving in cylinder volume **3412**. During the “down stroke” of piston rod **3460**, the liquid in vacuum volume **3275b** is pumped through vacuum end disk port **3291**, and flows through one-way valve **3293**, flap valve **3230c**, and separator plate port **3314**, arriving in cylinder volume **3412**.

7. The cycle continues with cycles comprising both “upstrokes” and “down strokes” of piston rod **3460**, with liquid motion through device **3000** as described in steps 3 through 6 above.

[0220] The ratio of the total volume of vacuum volumes **3275a** and **3275b** to delivery volume **3114** may be any range, such as 1:1, optionally about 3:1 or greater, or about 4:1 or greater. Since delivery piston **3130** only delivers liquid on one “half” of the pumping/vacuuming cycle, while vacuum piston **3270** works on both halves of the cycle, the ratio of the volume of liquid delivered to application tray **100** to the volume of liquid drawn from application tray **100** is 8:1 per cycle. The dual acting vacuum piston **3270** also provides vacuum during the half of the stroke where delivery piston **3130** is not delivering liquid, increasing the opportunity to retrieve liquid from application tray **100**, as well as clear additional liquid which leaked from application tray **100** into the oral cavity. Testing has shown a minimum 3:1 volumetric ratio of liquid vacuum to liquid delivery per stroke provided the necessary vacuum to minimize leakage into the oral cavity from application tray **100** when the tray has a marginal gingival seal, which may occur in embodiments of a universal (designed to fit a range of people) application tray **100** design.

[0221] In some embodiments vacuum piston **3270** is single acting. However, a dual acting vacuum piston **3270** may show some advantages.

[0222] In some embodiments, cylinder volume **3412** may have an air separator to reduce the foaming. Also, a breather vent may be required so that the pumping/vacuum system does

not over pressurize and lock/fail. The breather vent may be on the opposite side of the cylinder volume **3412** from the outlets of separator plate ports **3214** and **3314** to avoid liquid splashing out of the breather vent. In addition there may be a wall to split the cylinder volume **3412** into two halves, to further reduce the chance of liquid splashing out of the breather vent.

[0223] In general, cylinder volume **3412** is vented since more liquid is being delivered to cylinder volume **3412** from the vacuum system than is being drawn from the delivery system. The excess (air) is exhausted from a vent in cylinder volume **3412**. The vent could use a valve, such as an umbrella valve, so air can escape but cannot enter the reservoir from the same opening, or a 2-way valve or vent hole. To further reduce loss of liquid through the vent, a wall may be used to divide cylinder volume **3412** in two parts. One side contains the supply line, and the other side contains the vent. To optimize the separation of air from liquid in cylinder volume **3412**, an air separator may be placed in the reservoir, below the supply line. As the liquid drops from supply line into cylinder volume **3412**, it passes through an air separator, which may be a solid plate with holes. This allows the liquid to pass, while removing entrained air and helping to separate the two liquid states (liquid vs. gas). The air separator may have various designs, such as an angled solid shelf with holes, a spiraling ramp, a spiraling ramp with holes, two or more levels of angled shelves with holes, multiple spiraling ramps, similar to a multiple starting points for threads, (bottle caps, etc), sporadically located bosses that the liquid hits as it drops, assisting in separation.

[0224] In one embodiment, the hand-held device will be a self-contained, portable unit with a rechargeable battery, have a motor-driven piston pump for liquid delivery, have a mechanism to control the liquid flow, keep the temperature within a specified range, be modular in design, and have ergonomics well-suited to the user's hand. When the hand piece is in the base station, it will recharge the battery, refill the liquid reservoirs in the hand piece from those in the base station, and exchange samples and/or diagnostic information with the base station. It may also go through a cleaning process.

[0225] FIGs. 25a-25d show a representation example of an embodiment of a dental cleaning system **2000**. The figures show dental cleaning system **2000**, showing hand-held device **2220**, base station **2240**, and base station liquid reservoir **2250**. Base station liquid reservoir **2250** is used to refill the liquid reservoirs in device **2220**. Application tray **2100** is shown attached to device **2220**.

[0226] In this embodiment, base station liquid port **2245** is the conduit through which cleaning or treatment liquid passes from base station liquid reservoir **2250** to the liquid reservoirs in device **2220**. Liquid leaves base station liquid reservoir **2250** through base station liquid reservoir port **2255**, and enters the liquid reservoirs in device **2220** through port **2225**.

[0227] When in base station **2240**, the internal battery of device **2220** will recharge, and the liquid reservoirs in device **2220** will refill from those in base station **2240**. Any diagnostic information in device **2220** will be exchanged with base station **2240**. Device **2220** may also go through a cleaning process.

[0228] In other embodiments, a piston pump with check-valves will be used for liquid delivery.

[0229] In yet other embodiments, a rotary piston pump will be used for liquid delivery. This pump is known by those in the art, and the piston rotates as it reciprocates, therefore not needing any valves to operate. Reversing the rotation direction of the drive motor will reverse the liquid flow direction.

[0230] In still other embodiments diaphragm pumps, gear pumps, or double-action piston pumps will be used for liquid delivery. In the case of double-action piston pumps, when the liquid system is charged, this pump type has the benefit of reciprocating the direction of the liquid flow to the mouthpiece. Charged pneumatic cylinders, hand pump, or rotary pumps may be used to drive the system.

Example:

[0231] A test was performed in which 4 subjects used devices according to the present invention to assess efficacy of the devices and methods utilizing such devices from a germ removal and kill perspective. One of the endpoint methods used included bacterial viability determination via adenosine triphosphate (ATP) luminescence and total plate counts. Appropriate dilutions of the baseline samples were made in 0.1% peptone water. Both the rinsate and post-rinse samples were neutralized to stop antimicrobial actions and were diluted PO₄ neutralizer. Mouthpieces substantially similar to those depicted in FIGs 16-19 (universal mouthpiece) and FIGs 20-23 (custom-fit) were used in the test, one each of which was tested using water and the other with Cool Mint Listerine® mouth rinse (CML).

[0232] Total Cell Counts measuring colony forming units (CFU/ml), including total viable bacterial cells and total viable bad breath organisms, were used, respectively. The samples taken from the subjects were incubated under anaerobic conditions for 5 days at 35-37°C. The Relative Light Units (RLU) is a measure of the amount of ATP in a sample. The higher the RLU value, the more ATP is present, and the more live bacteria there are. Total cell counts (CFU/ml) and RLU were determined for each sample taken from the subjects both before (baseline) and post rinsing, as well as on rinsates collected after rinsing.

[0233] The subjects rinsed the oral cavity with 5 mL water for 10 seconds. The baseline example was collected by having the subject expectorate the rinse water into a conical tube, and then expectorating an additional 1ml of saliva into that tube. Each subject then rinsed the oral cavity, 2 with water using the respective mouthpiece designs, and 2 with the Cool Mint Listerine using the respective mouthpiece designs. The rinsate was then collected for each subject and 20 mL was placed in a conical tube. Each subject then repeated the rinse with 5 mL of water for 10 seconds and, as before, the rinse and the post-rinse sample collected in a conical tube. The samples were neutralized, diluted, plated and then incubated for 5 days and the cell counts and ATP measured. Results are presented in Tables 1-3. Subject 1 BL used water as the liquid and the universal mouthpiece. Subject 2 BL used water as the liquid and the custom-fit mouthpiece. Subject 3 BL used CML as the liquid and the universal mouthpiece. Subject 4 BL used CML as the liquid and the custom-fit mouthpiece.

Table 1

Total Organisms	Average Counts	% Reduction from baseline	log reduction
Subject 1 BL	1.88E+07		
Subject 2 BL	2.07E+07		
Subject 3 BL	1.13E+08		
Subject 4 BL	1.93E+08		
Subject 1 Rinsate	7.40E+04	99.6%	2.40
Subject 2 Rinsate	1.90E+04	99.9%	3.04
Subject 3 Rinsate	2.00E+03	100.0%	4.75
Subject 4 Rinsate	3.00E+03	100.0%	4.81
Subject 1 Post	7.50E+05	96.0%	1.40
Subject 2 Post	3.02E+06	85.4%	0.84
Subject 3 Post	8.70E+06	92.3%	1.11
Subject 4 Post	7.20E+06	96.3%	1.43

Table 2:

Bad Breath Organisms	Average Counts	% Reduction from baseline	log reduction
Subject 1 BL	5.30E+06		
Subject 2 BL	2.70E+06		
Subject 3 BL	2.10E+07		
Subject 4 BL	3.50E+07		
Subject 1 Rinsate	3.10E+04	99.4%	2.23
Subject 2 Rinsate	1.00E+03	100.0%	3.43
Subject 3 Rinsate	1.50E+03	100.0%	4.15
Subject 4 Rinsate	1.00E+03	100.0%	4.54
Subject 1 Post	6.50E+05	87.7%	0.91
Subject 2 Post	4.40E+05	83.7%	0.79
Subject 3 Post	2.80E+06	86.7%	0.88
Subject 4 Post	2.10E+06	94.0%	1.22

Table 3:

ATP	RLU	% Reduction from baseline	log reduction
Subject 1 BL	7.44E+04		
Subject 2 BL	3.93E+04		
Subject 3 BL	2.18E+05		
Subject 4 BL	3.12E+05		
Subject 1 Rinsate	3.14E+04	57.7%	0.37
Subject 2 Rinsate	2.85E+04	27.4%	0.14
Subject 3 Rinsate	2.81E+04	87.1%	0.89
Subject 4 Rinsate	2.61E+04	91.6%	1.08
Subject 1 Post	3.01E+04	59.5%	0.39
Subject 2 Post	2.90E+04	26.1%	0.13
Subject 3 Post	7.04E+04	67.7%	0.49
Subject 4 Post	3.40E+04	89.1%	0.96

Conclusions

[0234] Post-rinse plate count data demonstrates approximate significant reduction for both water rinse and CML rinse. Analysis of the rinsate plate count data also demonstrates a significant reduction from the baseline in the water rinse, and even more significant reduction from the baseline in the CML rinse. The log reductions present in the water rinsate suggests mechanical bacterial removal during treatment in the absence of antimicrobials. The higher log reductions present in the CML rinsate suggests a combination of mechanical and antimicrobial activity during treatment.

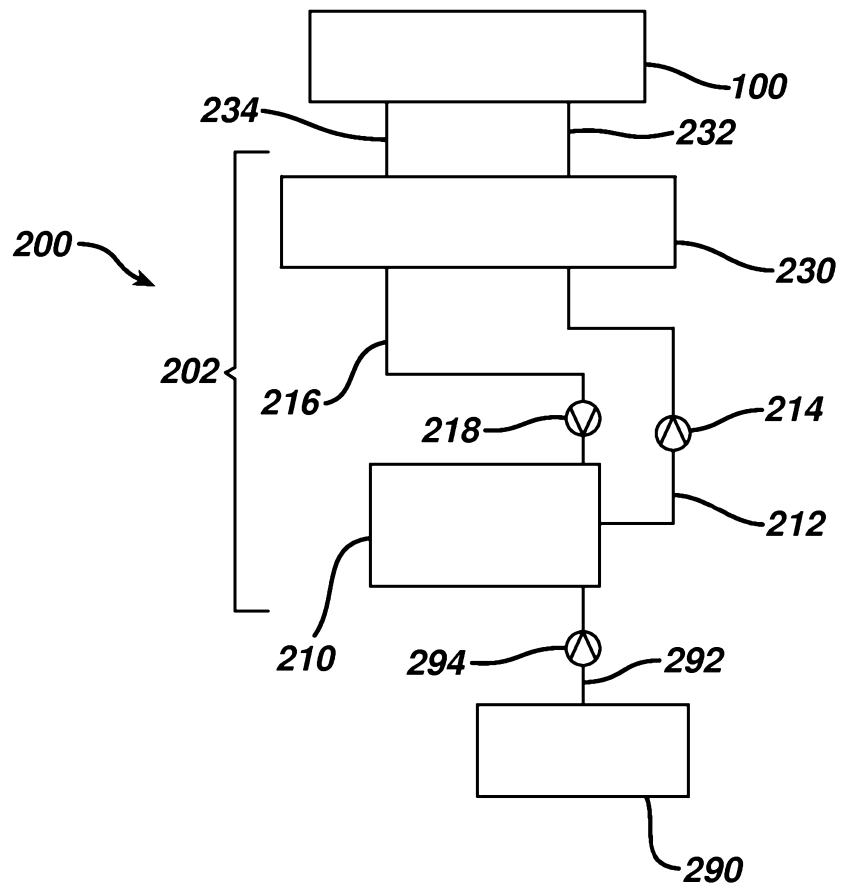
[0235] Though several embodiments have been described, it should be understood that the scope of the present invention embraces other possible variations, being limited only by the contents of the accompanying claims, which includes the possible equivalents.

Claims

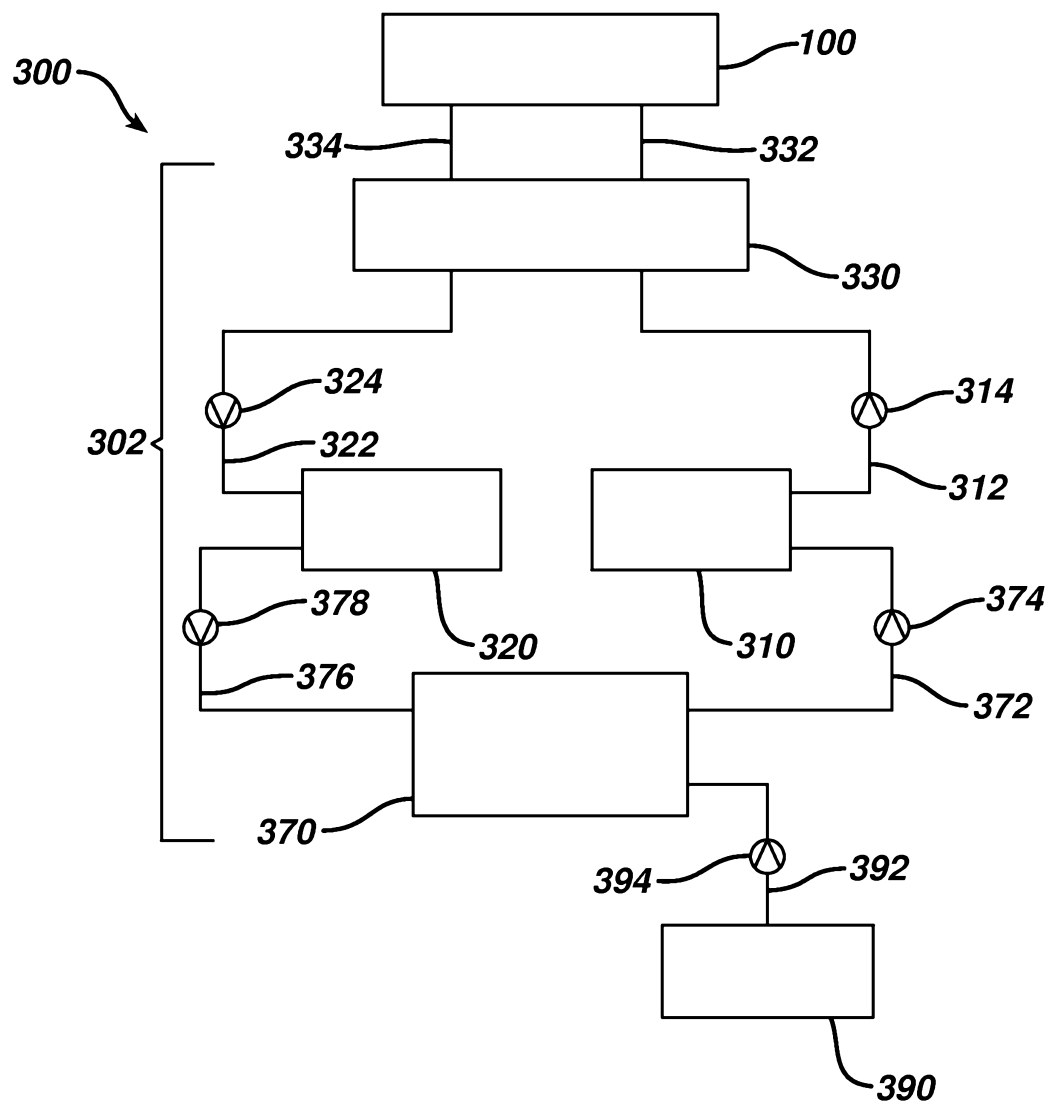
1. A device for directing a liquid onto a plurality of surfaces of an oral cavity of a mammal, said device comprising,
 - a chamber for maintaining said liquid proximate said plurality of surfaces, said chamber defined by front and rear inner walls and a base inner wall of said device, said base wall extending between said front and rear inner walls, but not comprising a rear gum-sealing membrane defining said chamber, said front and rear inner walls comprising a plurality of openings,
 - a first manifold for containing a first portion of said liquid and providing said first portion to said chamber through said openings of said front inner wall,
 - a second manifold for containing a second portion of said liquid and providing said second portion to said chamber through said openings of said rear inner wall,
 - a first port for conveying said first portion of liquid to and from said first manifold,
 - a second port for conveying said second portion of liquid to and from said second manifold; and
 - means for providing an effective seal of said device within said oral cavity.
2. The device of claim 1 further comprising means for attaching said device to means for providing said liquid to said device.
3. The device of claim 2 wherein said means for attaching comprises a quick disconnect structure for attaching said device to said means for providing said liquid to said device.
4. The device of claim 2 wherein said means for attaching comprises a support plate fixedly attached to the front of said device and having first and second ports extending there through, said support plate comprising a structure for attaching said device to said means for providing liquid to said device.
5. The device of claim 1 comprising a plurality of front lumens connected by said first manifold and a plurality of rear lumens connected by said second manifold.
6. The device of claim 1 wherein the number, location and cross-sectional geometry of said openings are effective to provide a spray pattern effective to provide a beneficial effect to the oral cavity.

7. The device of claim 1 comprising a top piece and a bottom piece for providing substantially simultaneous contact of a plurality of surfaces of both top and bottom sections of said oral cavity.
8. The device of claim 1 wherein the cross-sectional geometry of said openings is selected from the group consisting of circular, elliptical and trapezoidal.
9. The device of claim 1 comprising a single piece for providing contact of said plurality of surfaces to a top or bottom section of the oral cavity.
10. The device of claim 1 wherein said base wall comprises a flexible membrane for providing said effective seal.
11. The device of claim 10 comprising a flexible gum-sealing membrane for providing said effective seal.
12. A device for directing a liquid onto a plurality of surfaces of an oral cavity of a mammal, said device substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

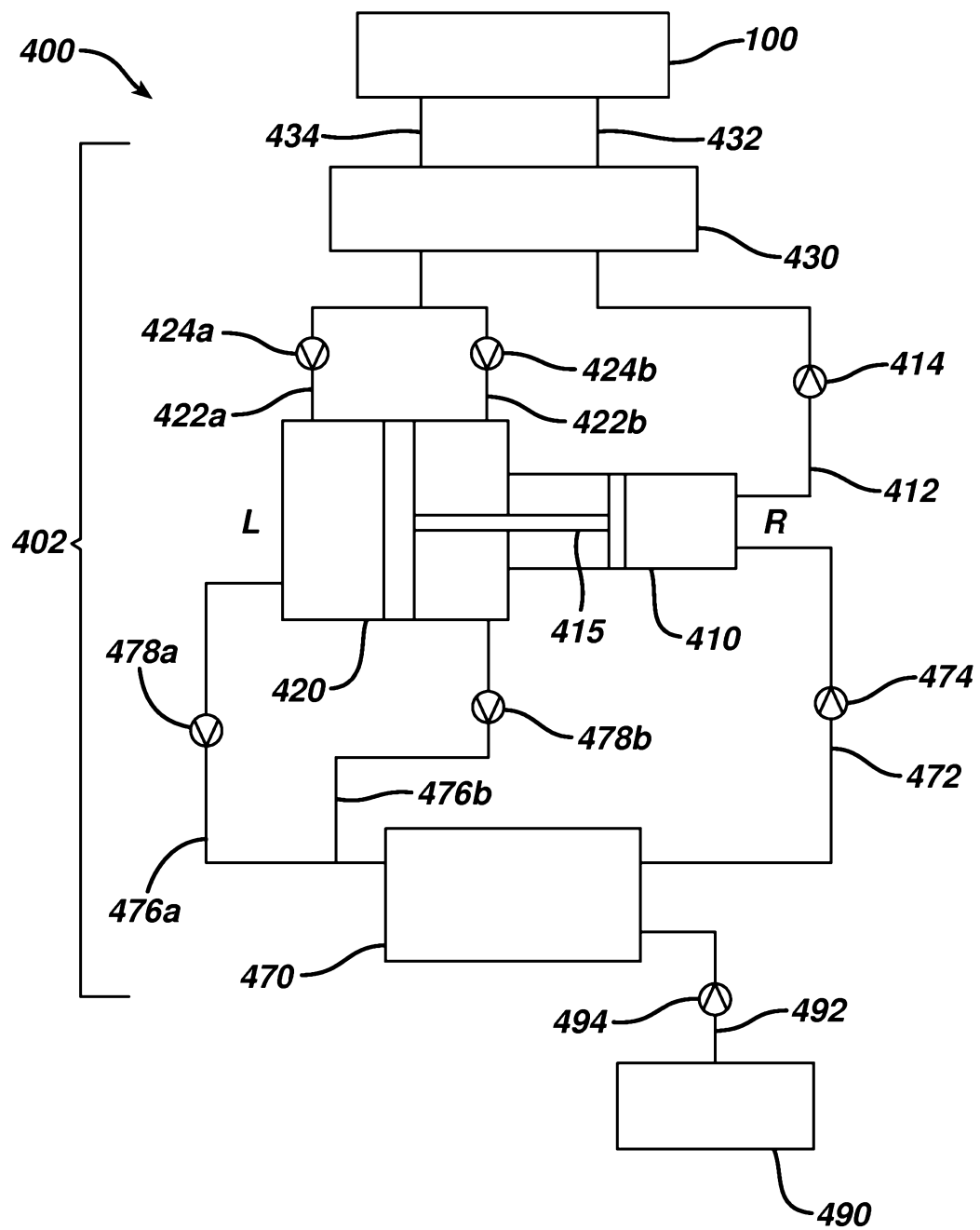
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FIG. 1

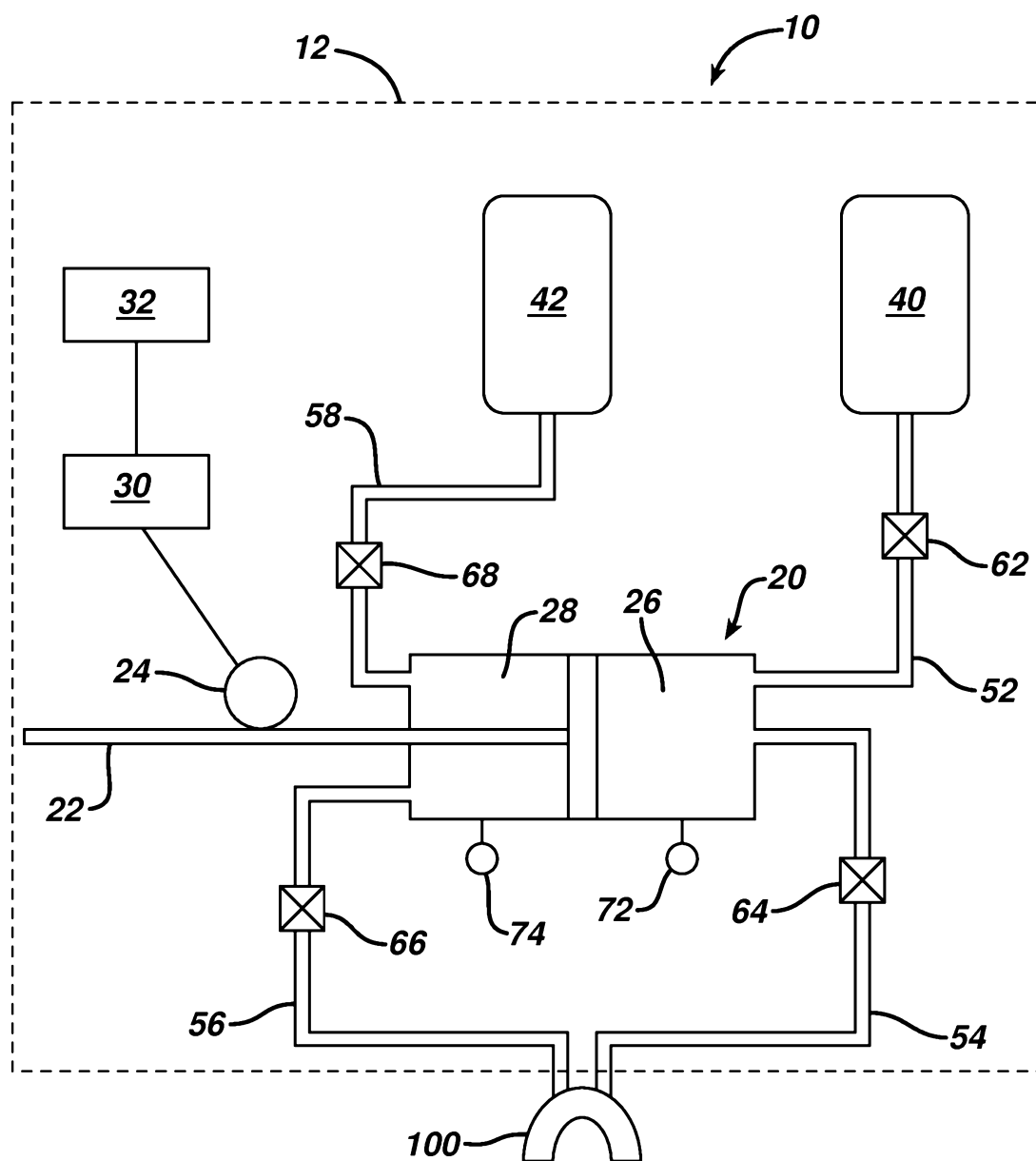
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FIG. 2

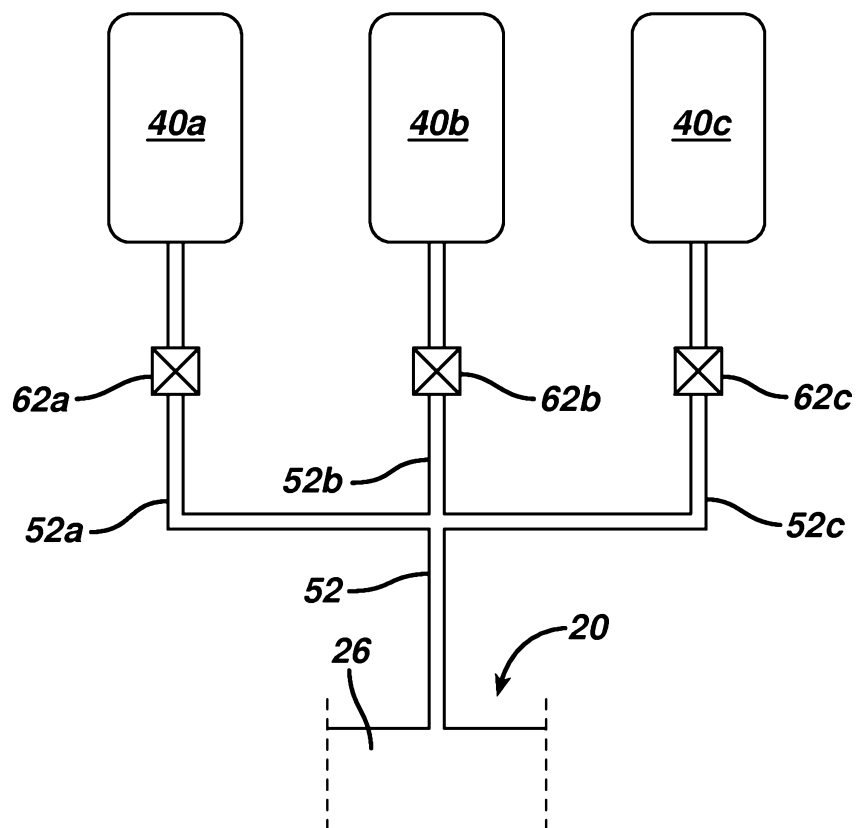
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FIG. 3

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FIG. 4

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FIG. 5

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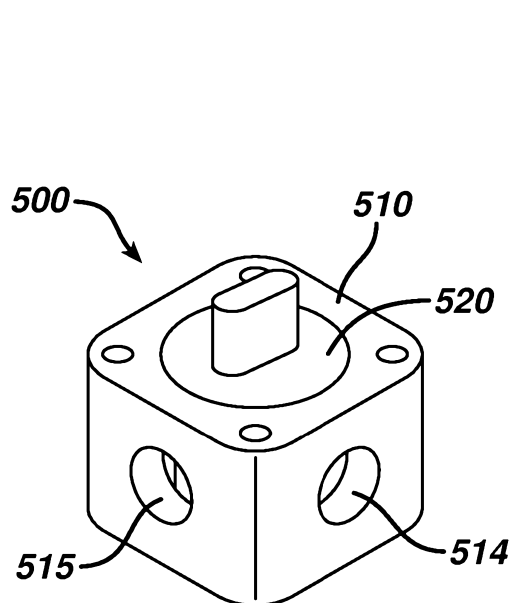


FIG. 6a

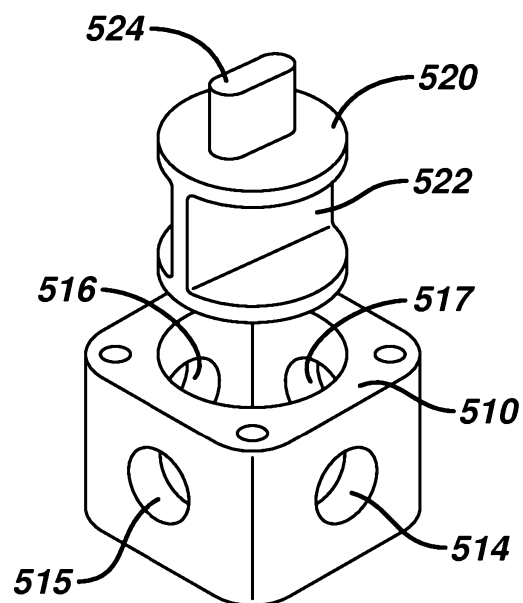


FIG. 6b

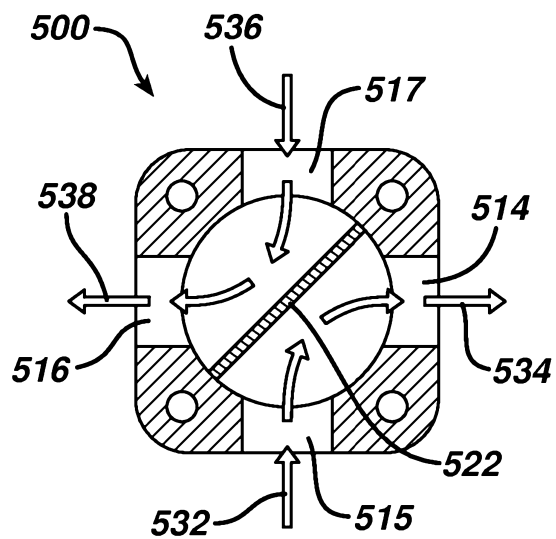


FIG. 6c

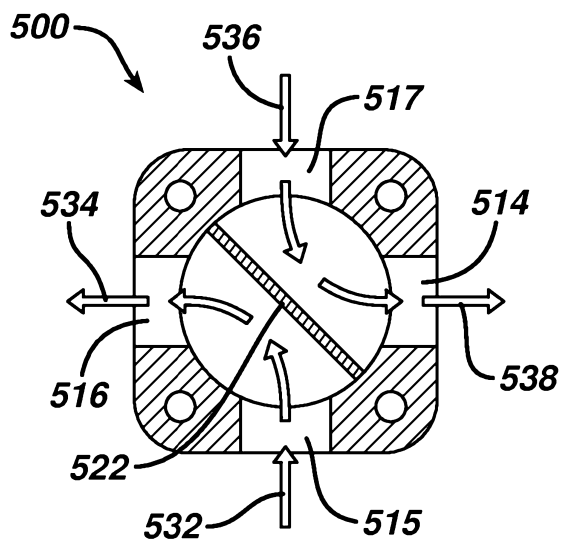


FIG. 6d

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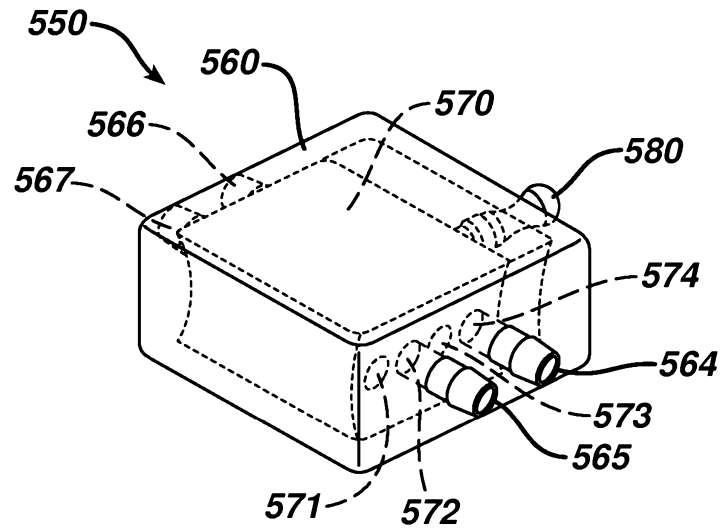


FIG. 7a

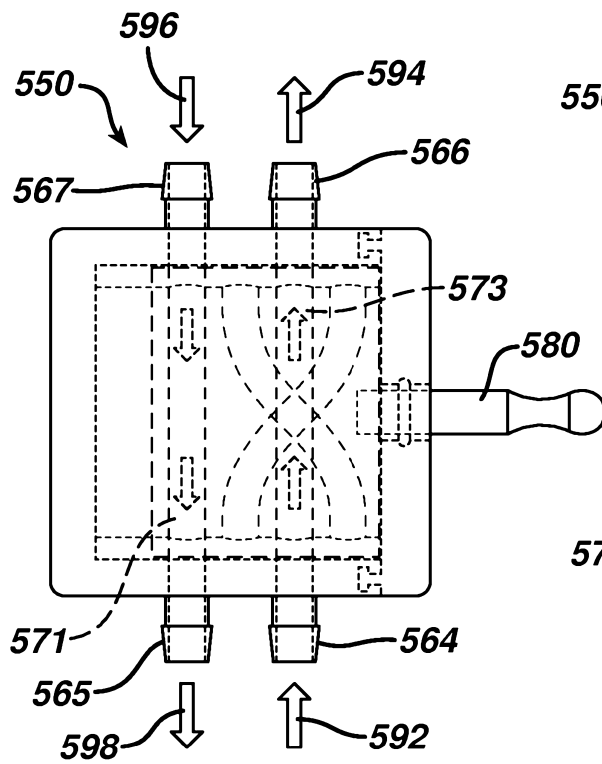


FIG. 7b

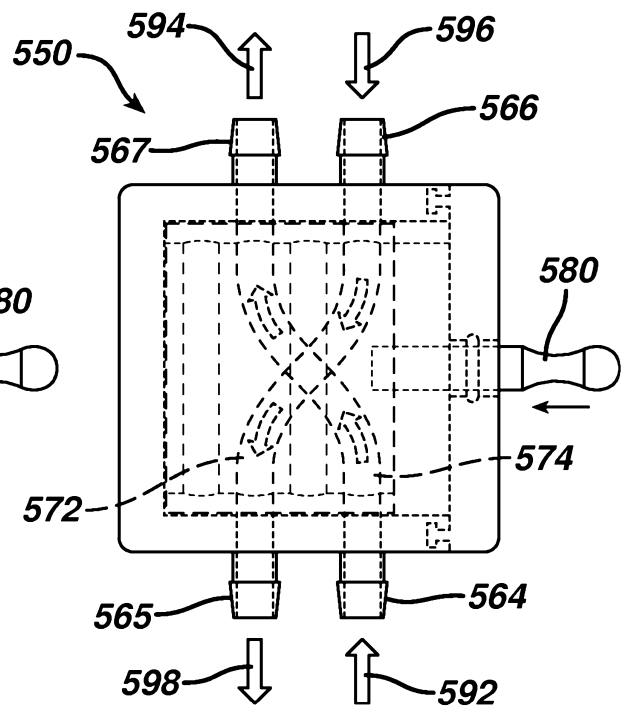
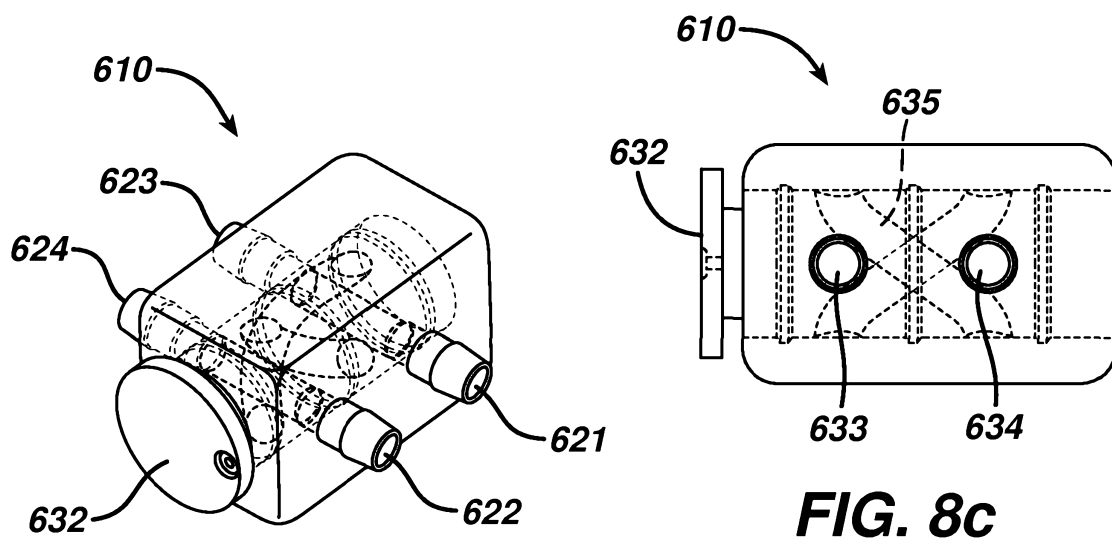
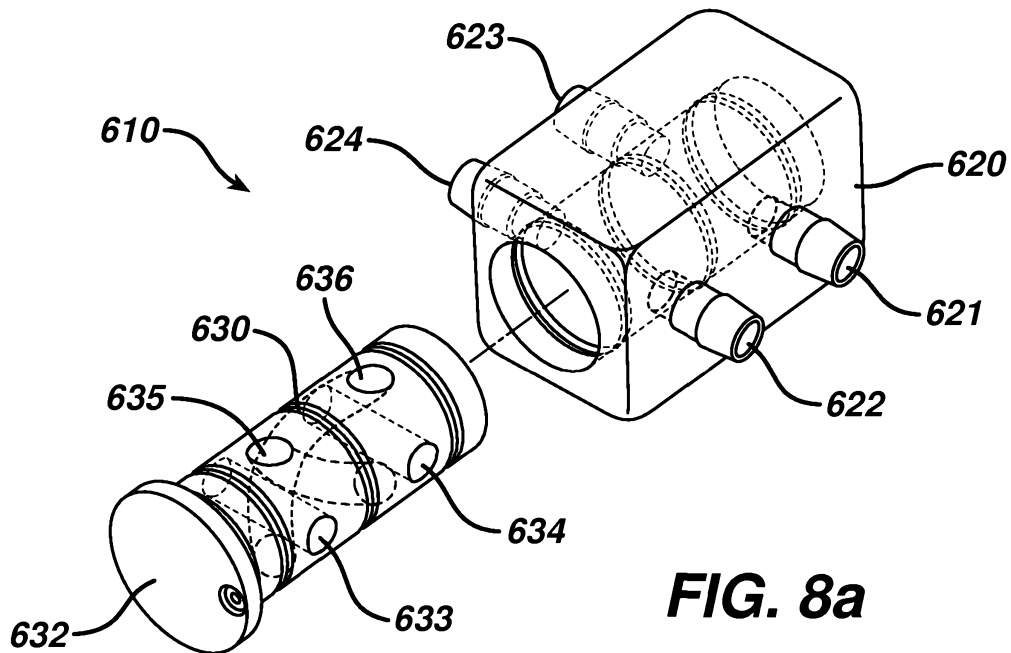
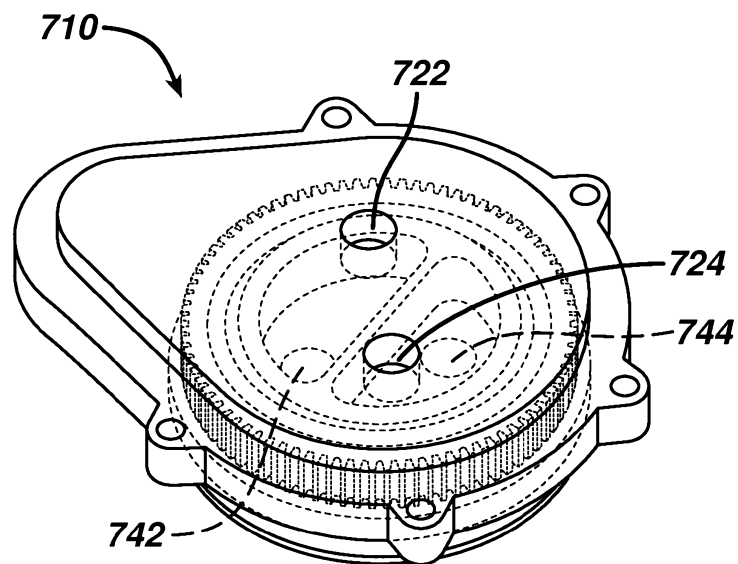
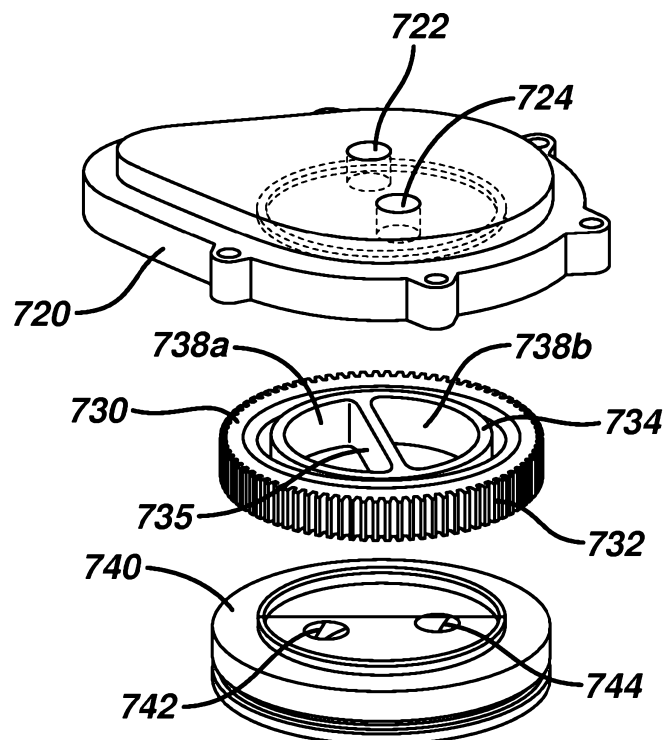


FIG. 7c

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**FIG. 9a****FIG. 9b**

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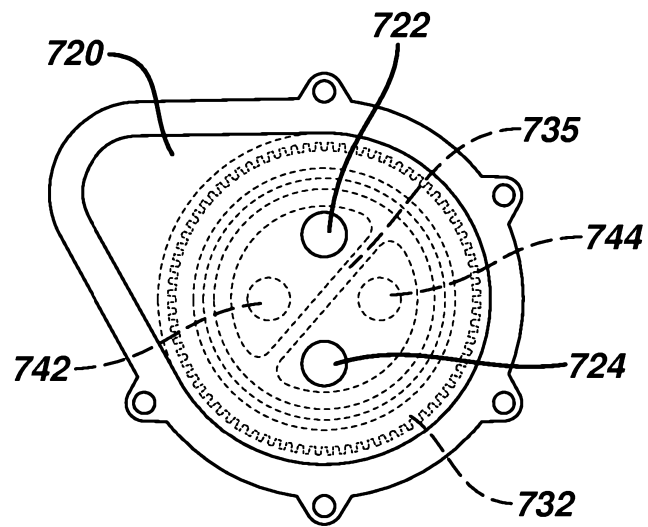


FIG. 9c

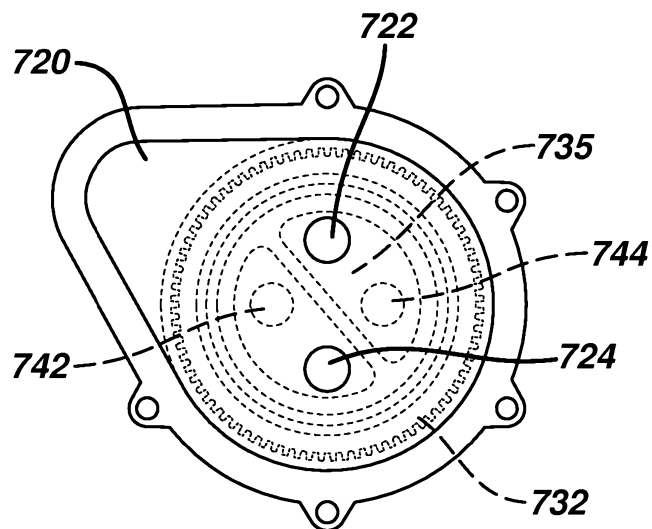
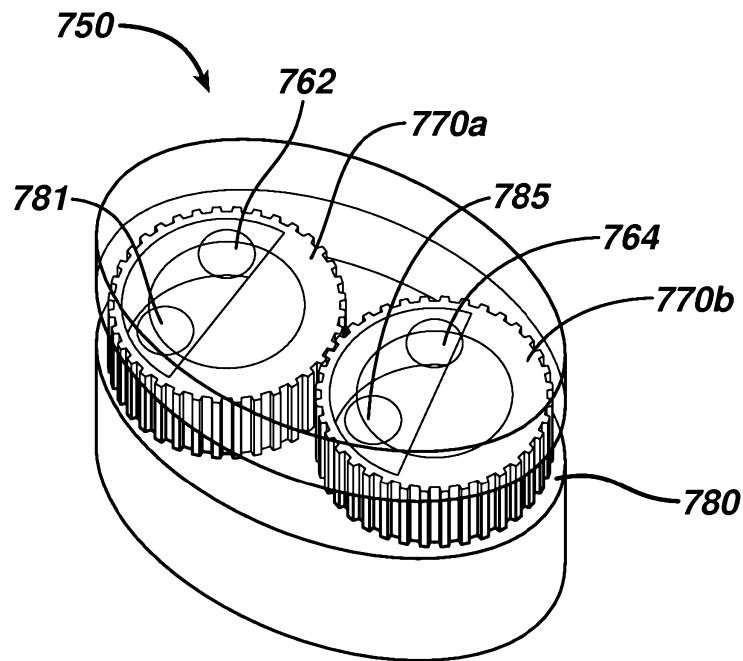
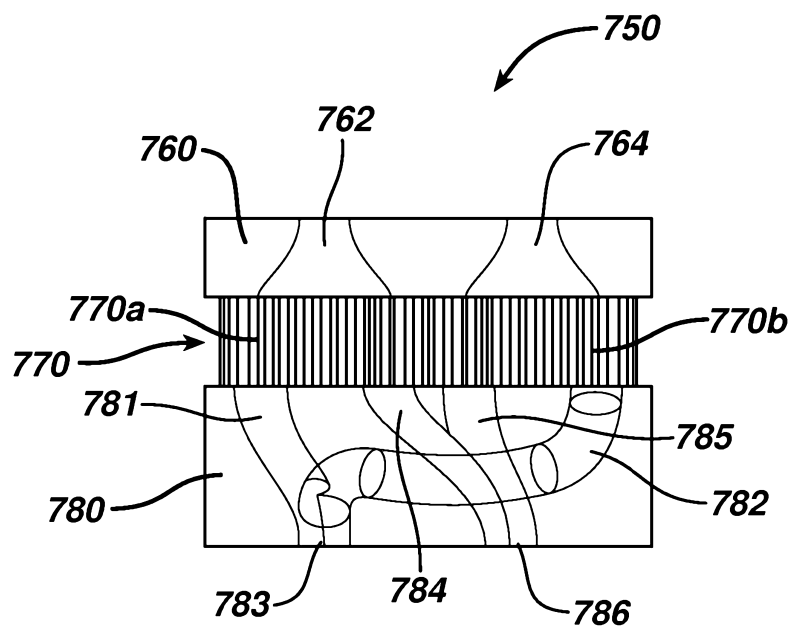


FIG. 9d

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**FIG. 10a****FIG. 10b**

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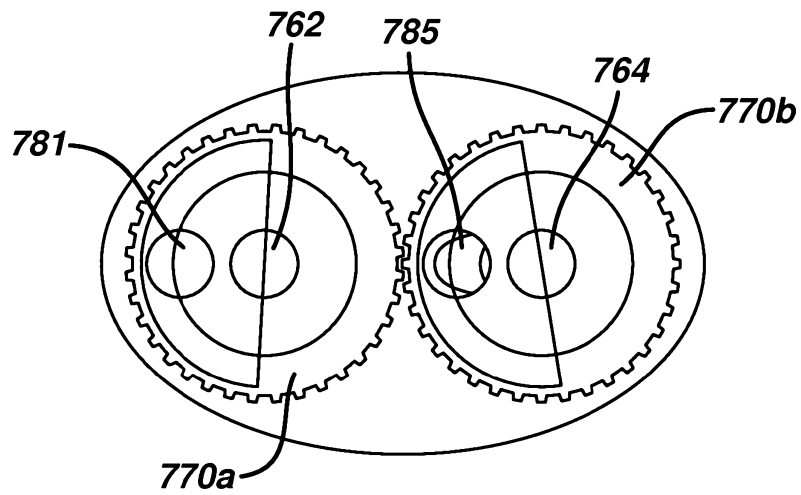


FIG. 10c

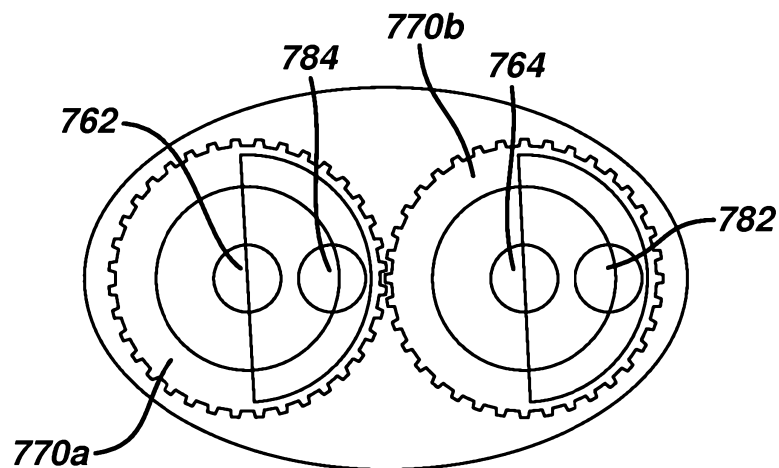
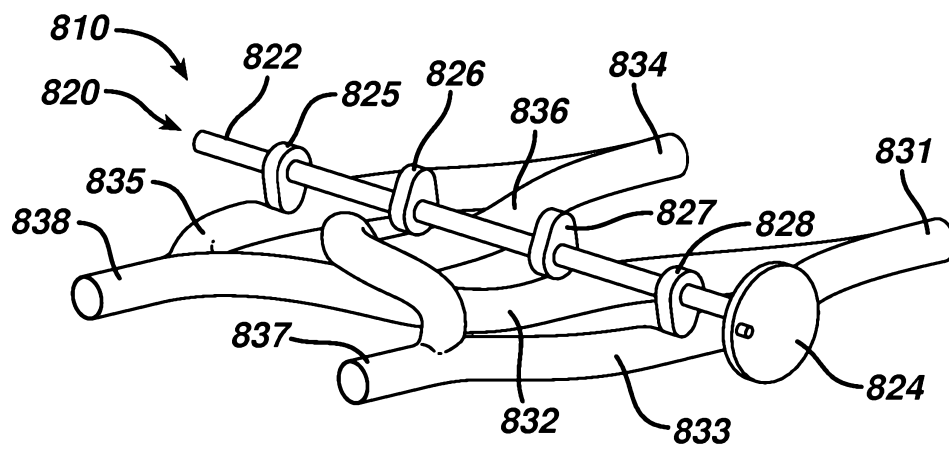


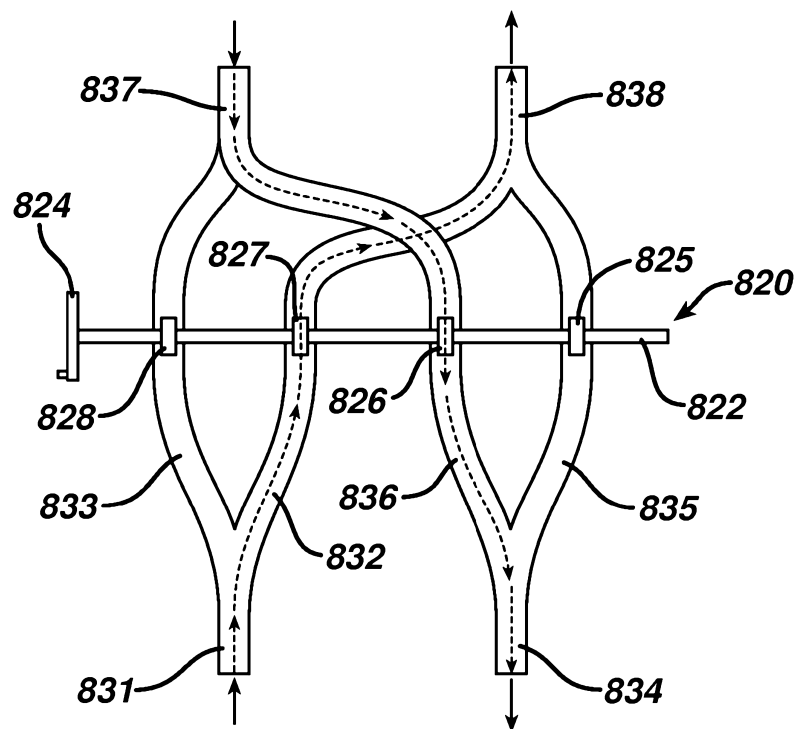
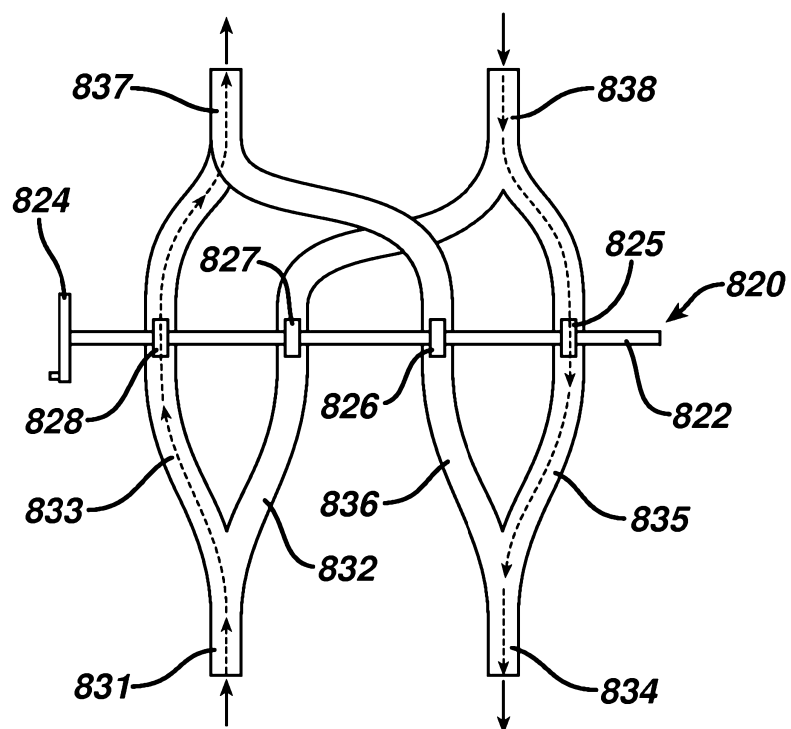
FIG. 10d

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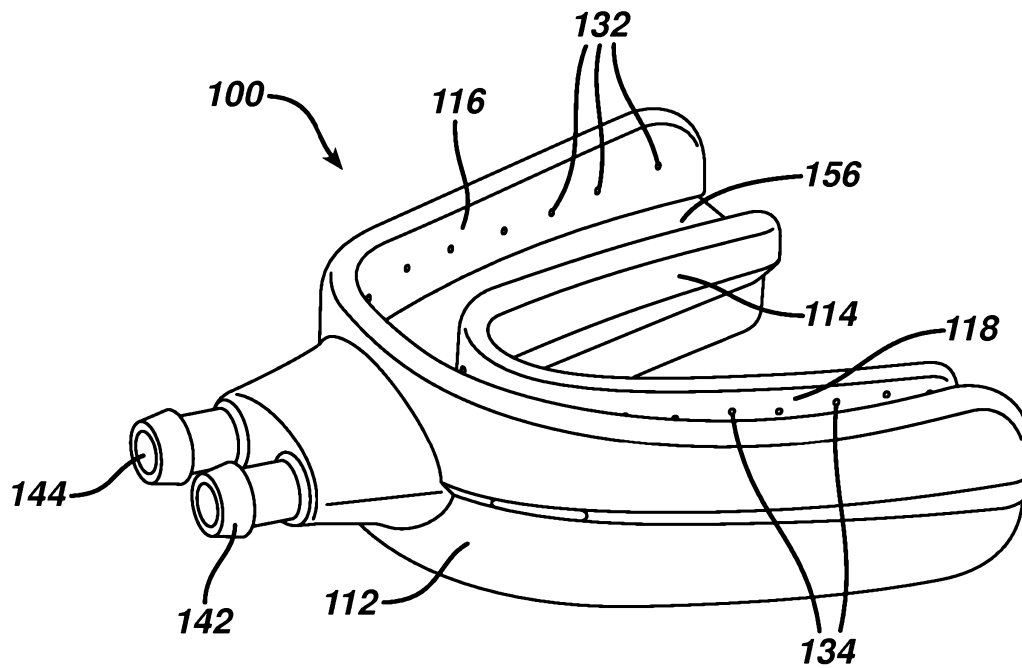
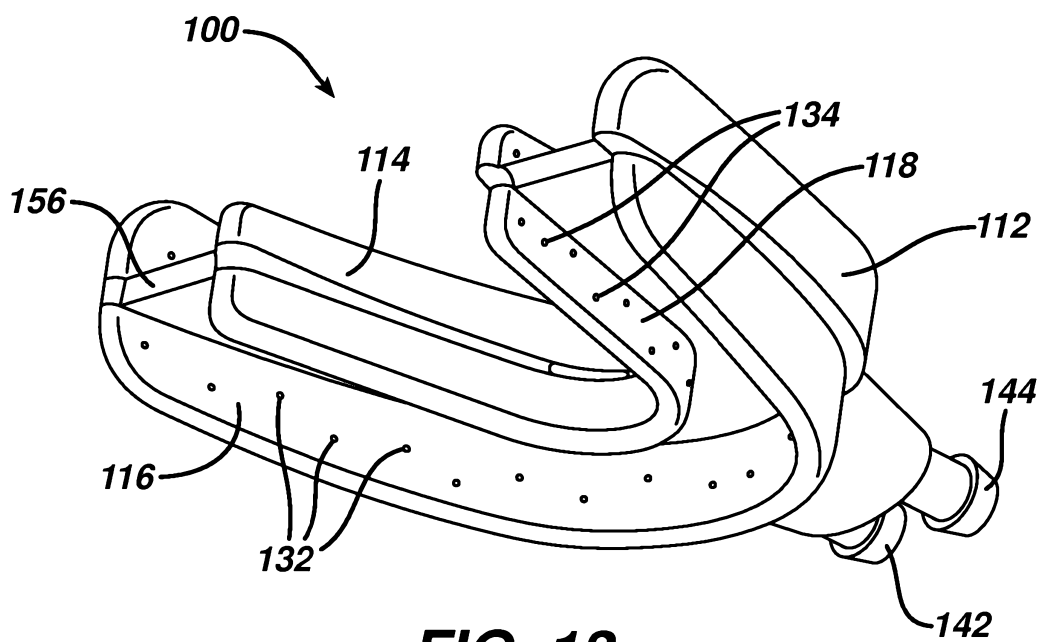
FIG. 11a



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FIG. 11b**FIG. 11c**

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**FIG. 12****FIG. 13**

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FIG. 14

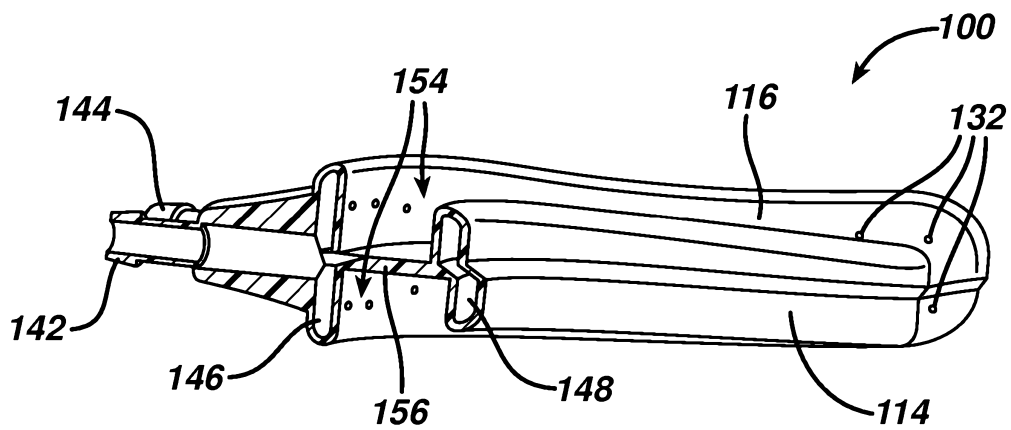
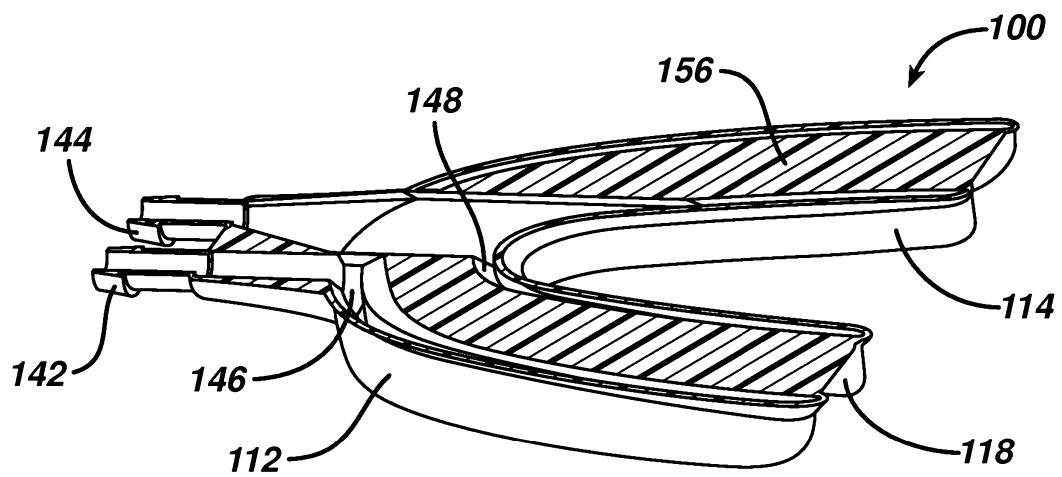
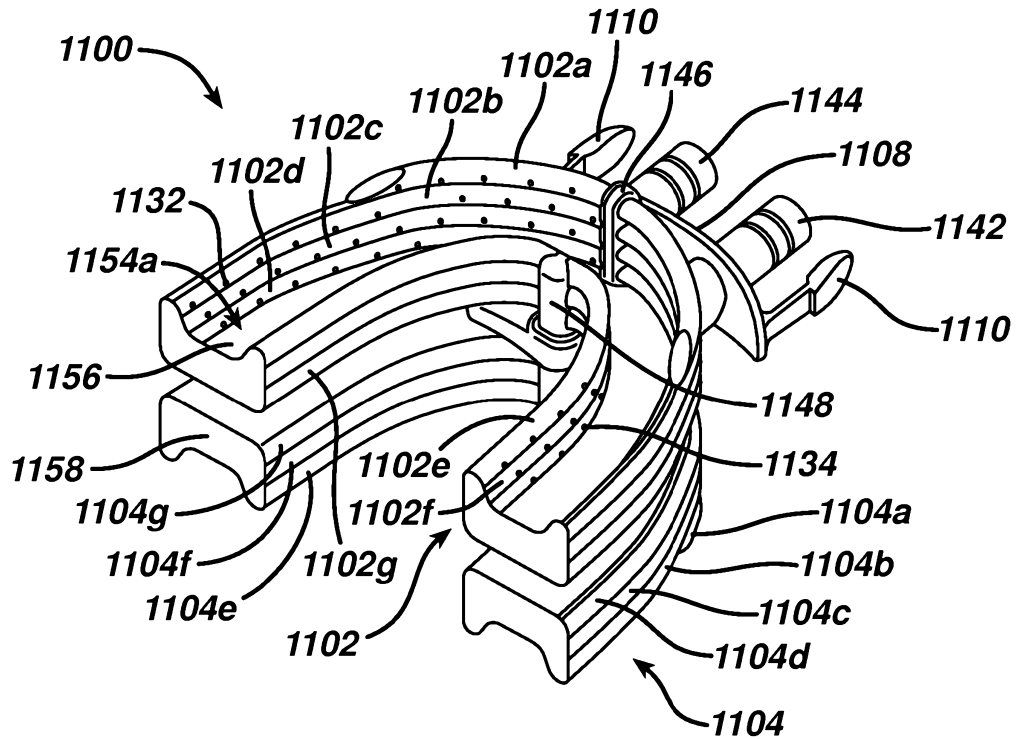
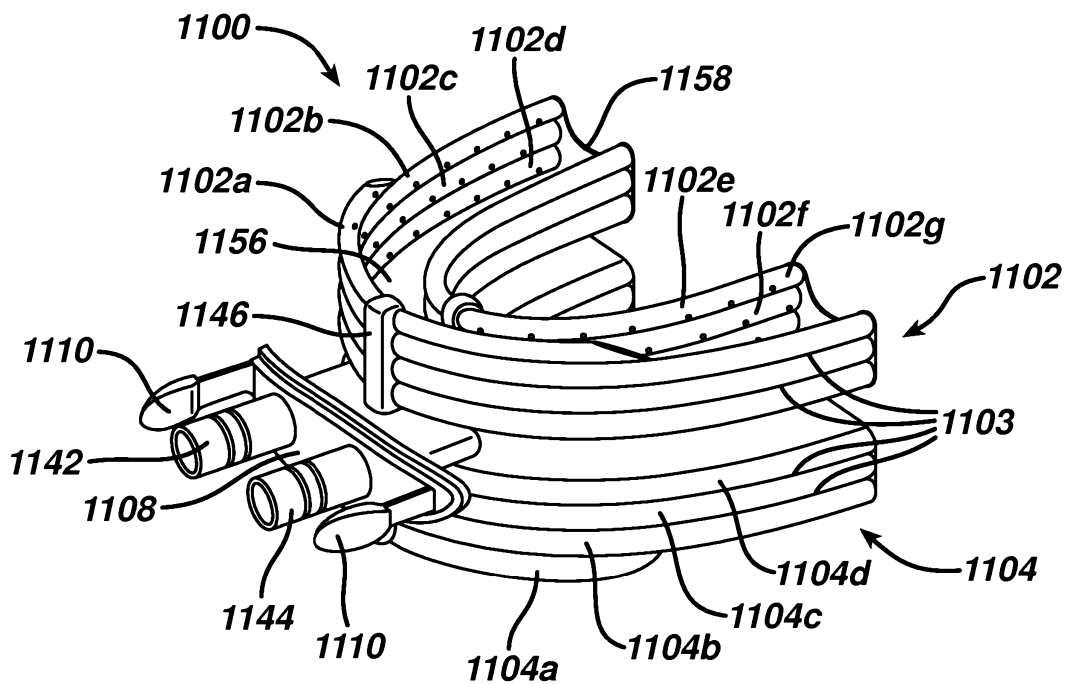


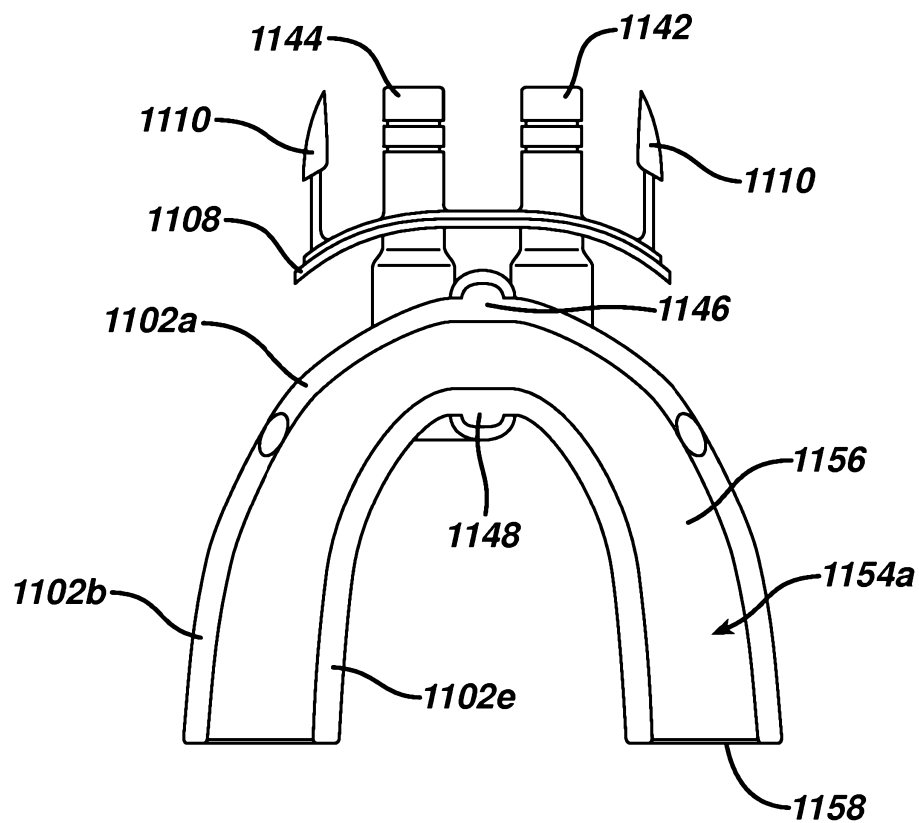
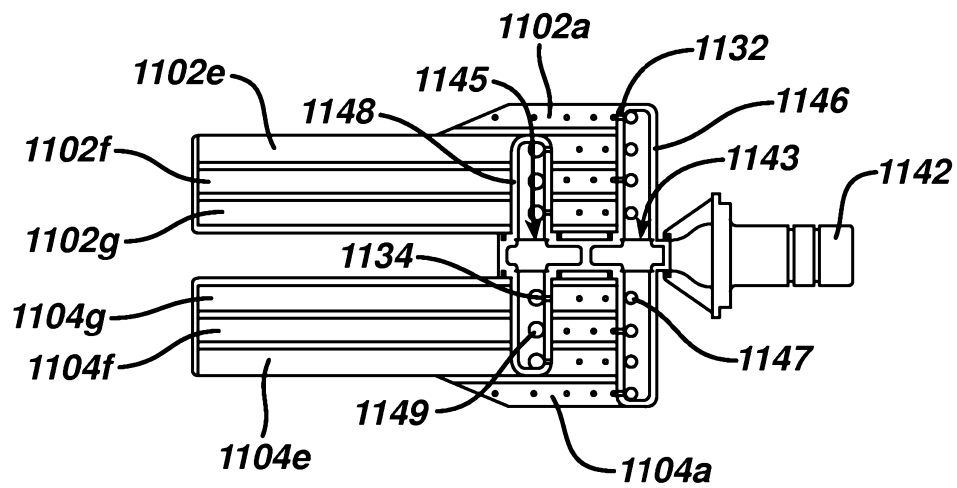
FIG. 15



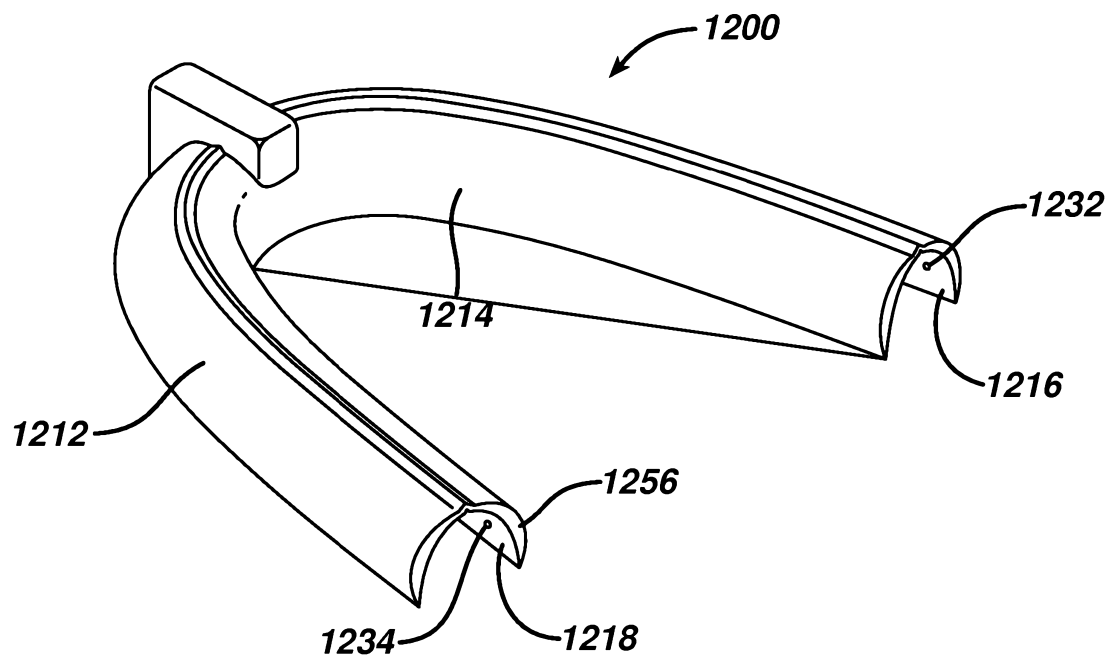
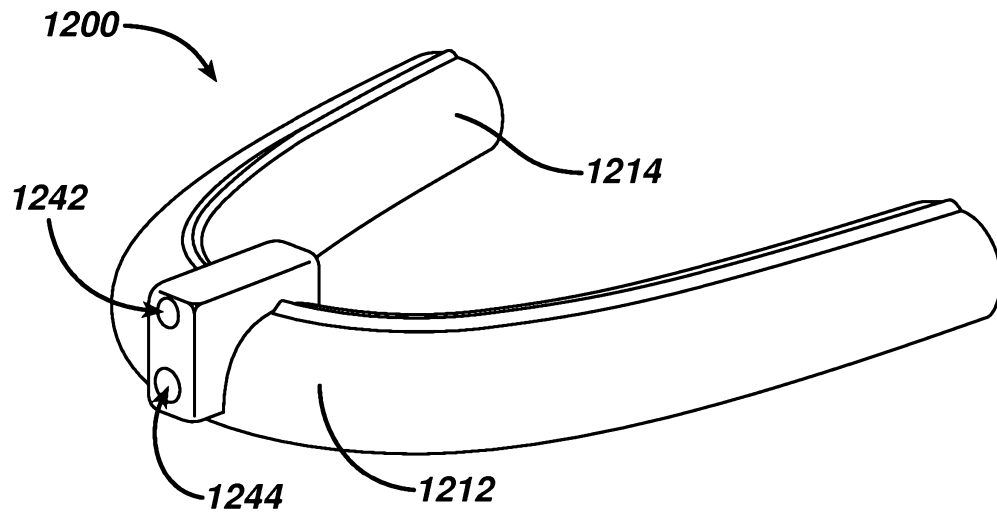
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FIG. 16**FIG. 17**

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**FIG. 18****FIG. 19**

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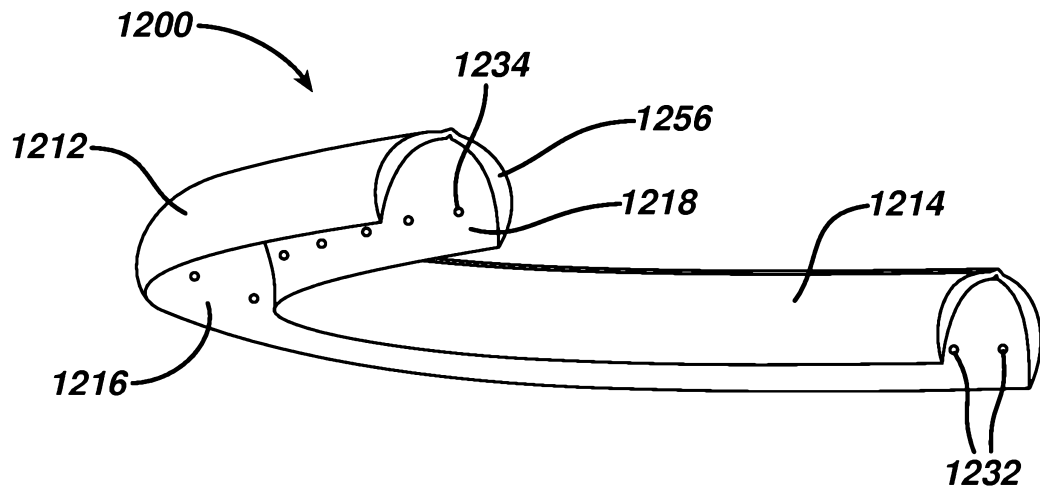


FIG. 22

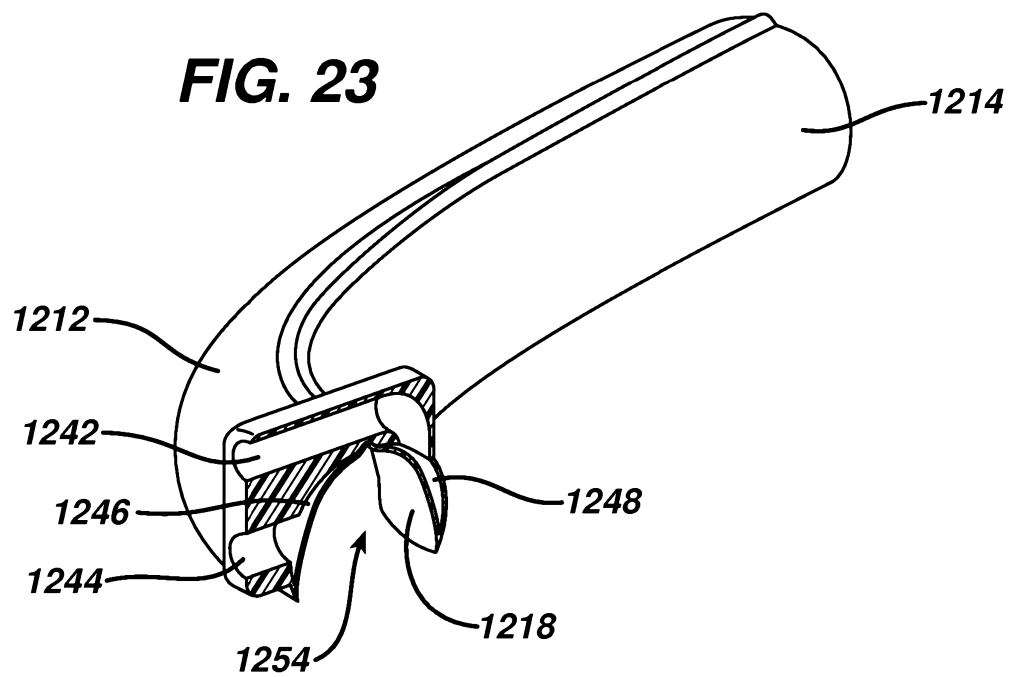
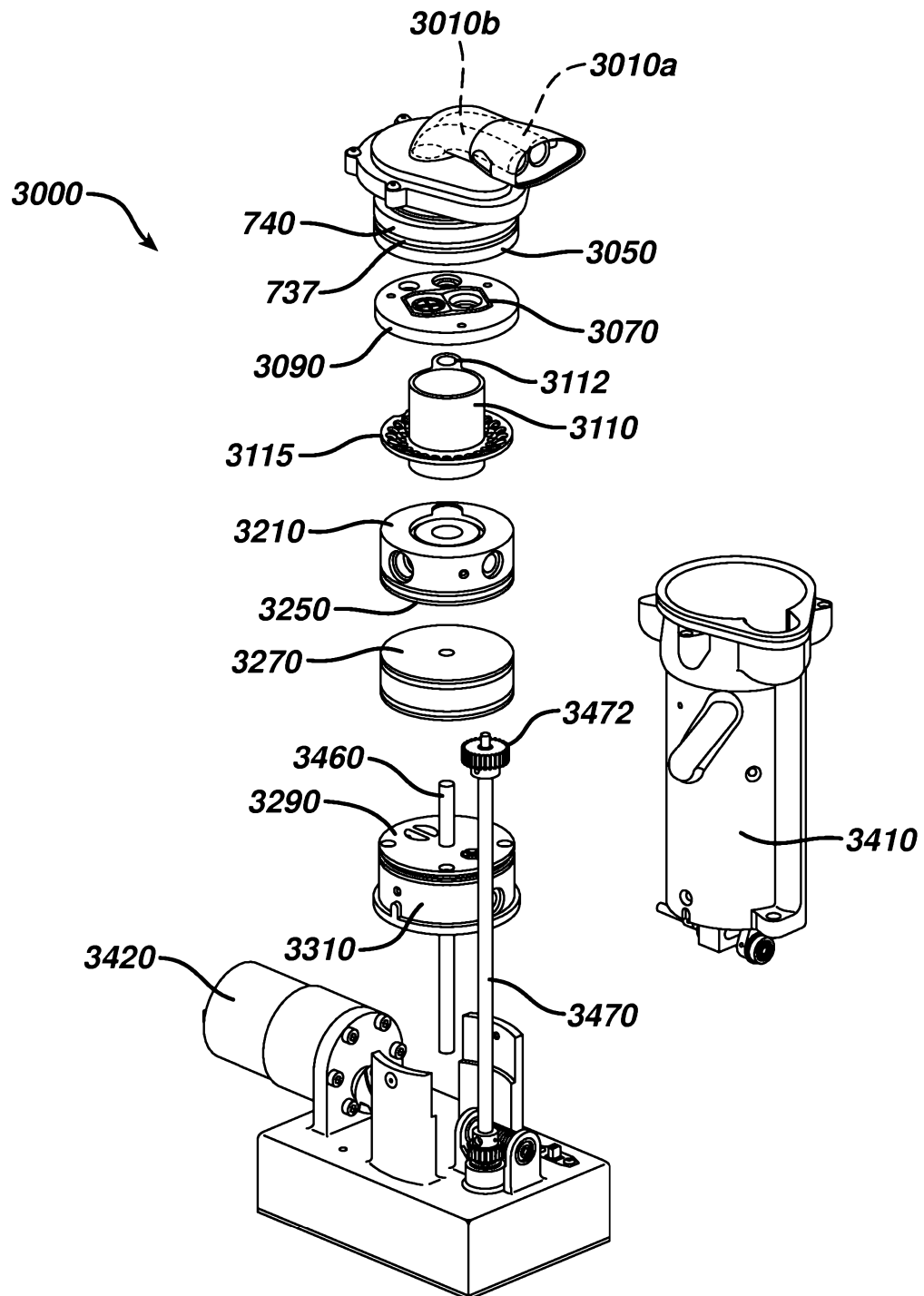


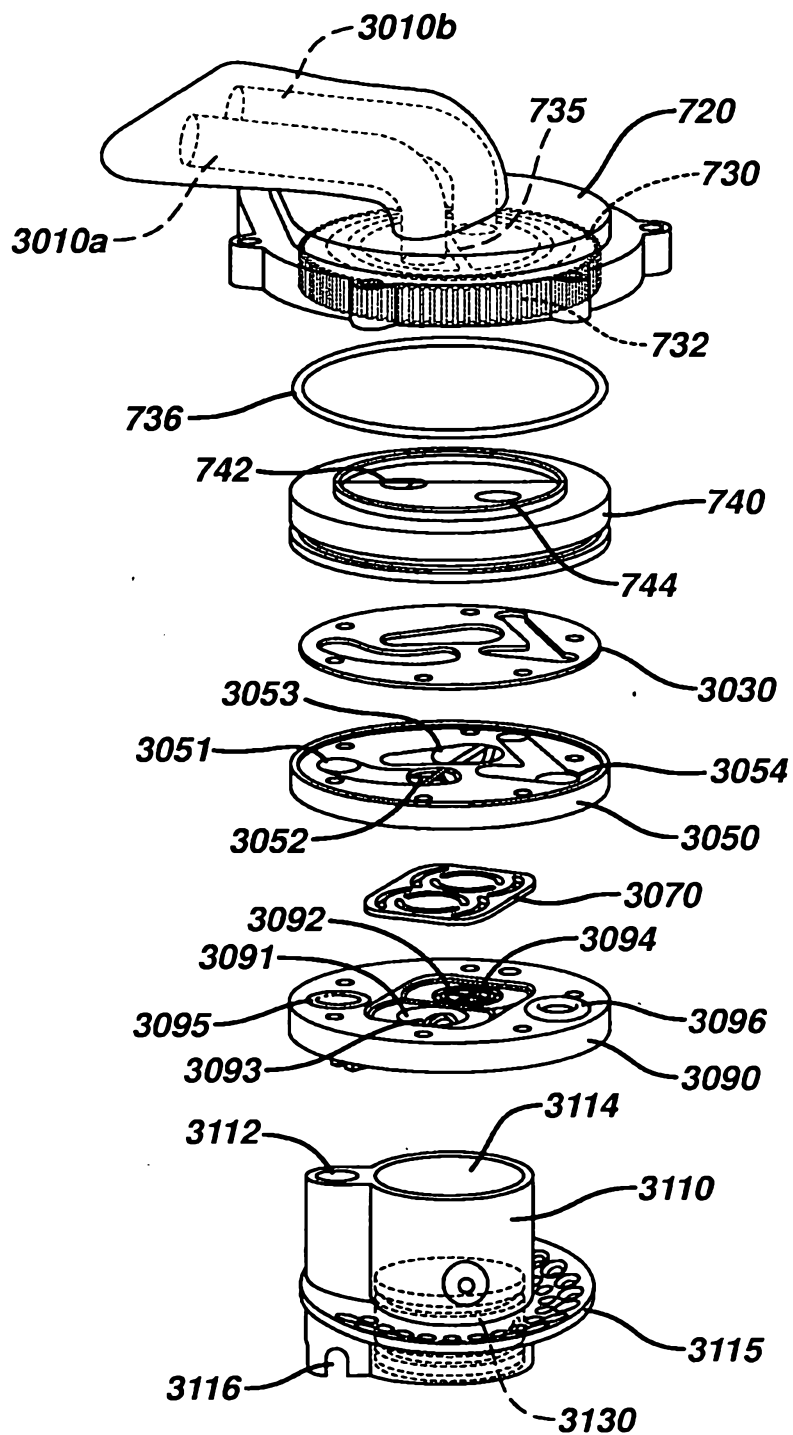
FIG. 23

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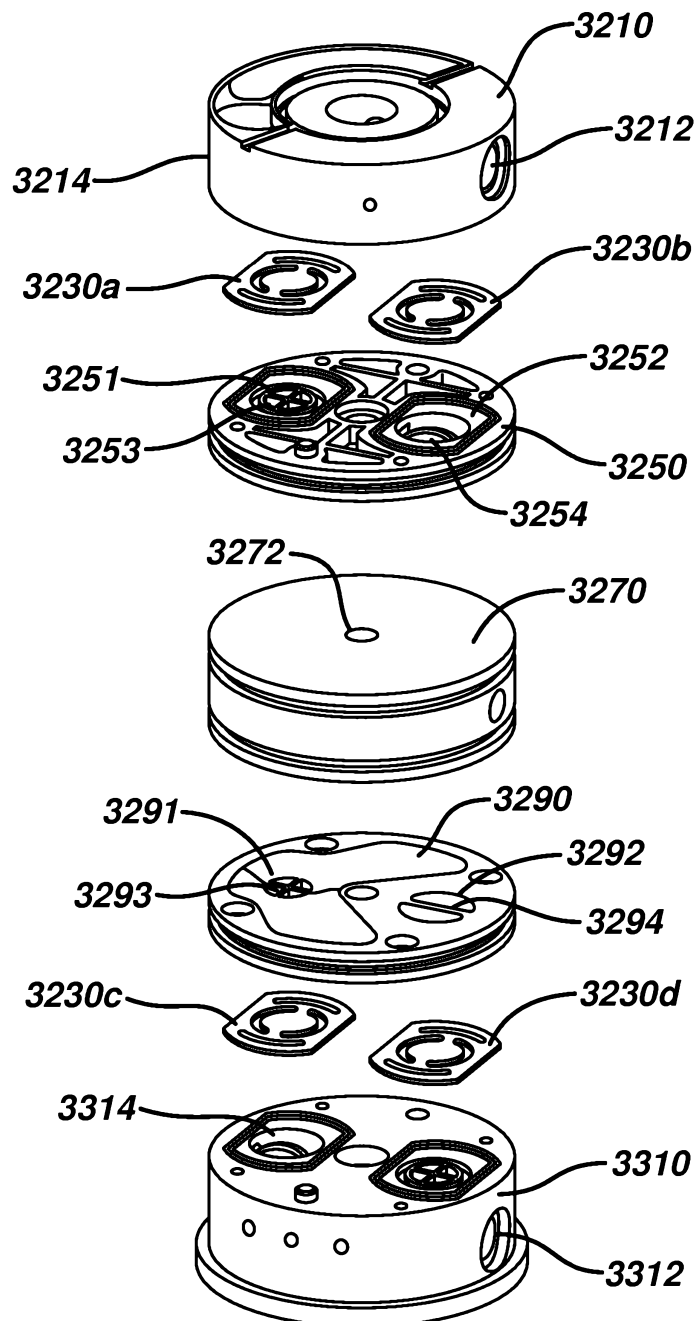
FIG. 24a

REPLACEMENT SHEET

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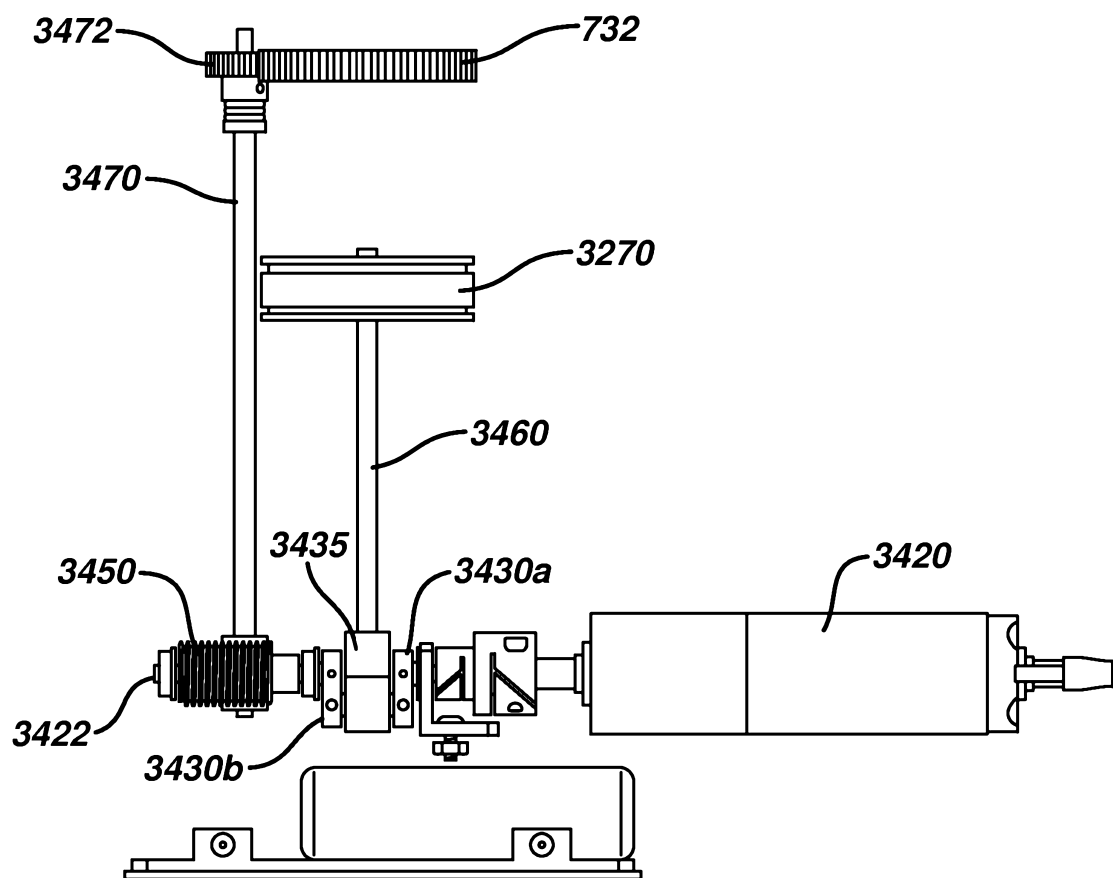
FIG. 24b

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FIG. 24c

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FIG. 24d



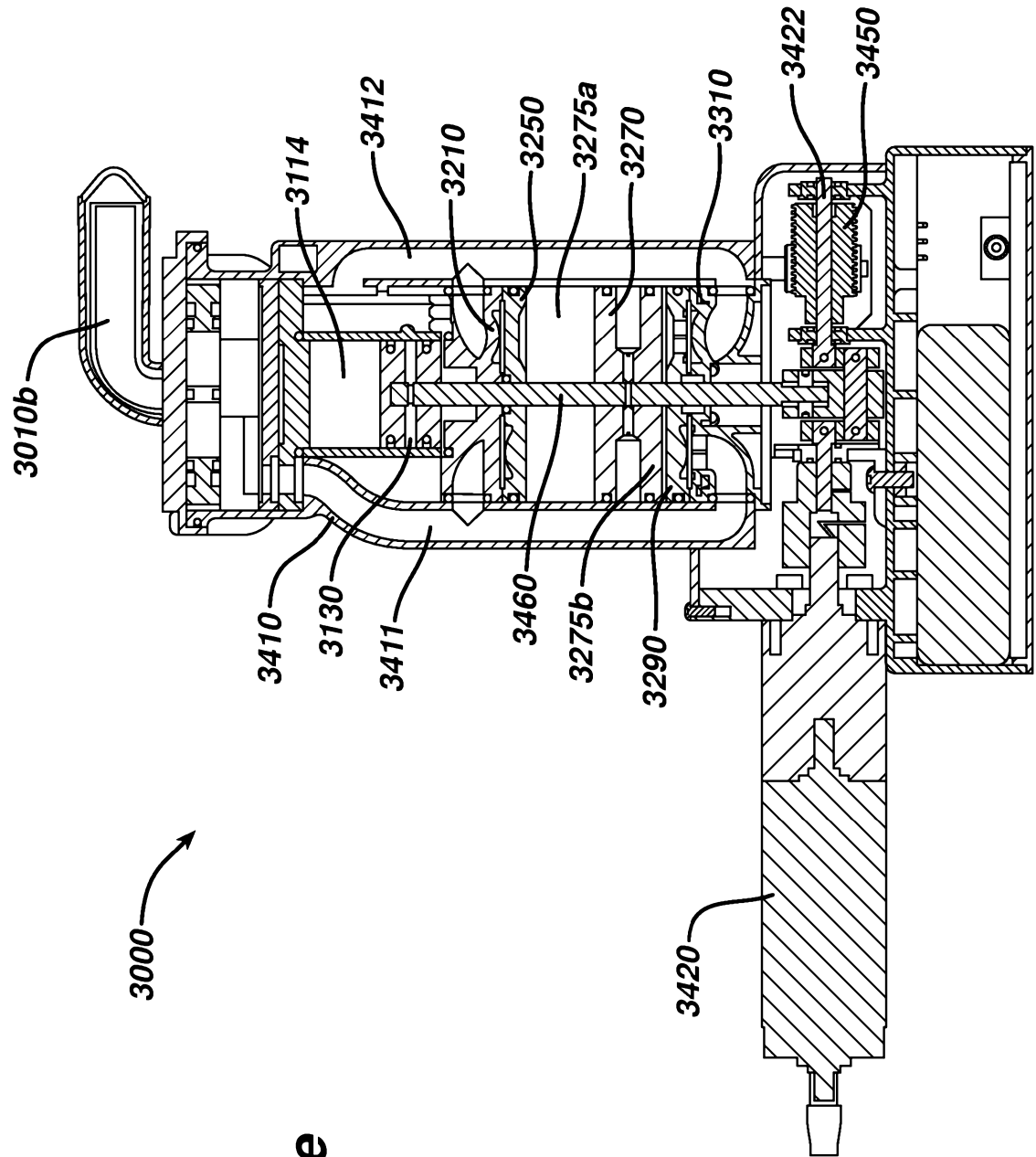
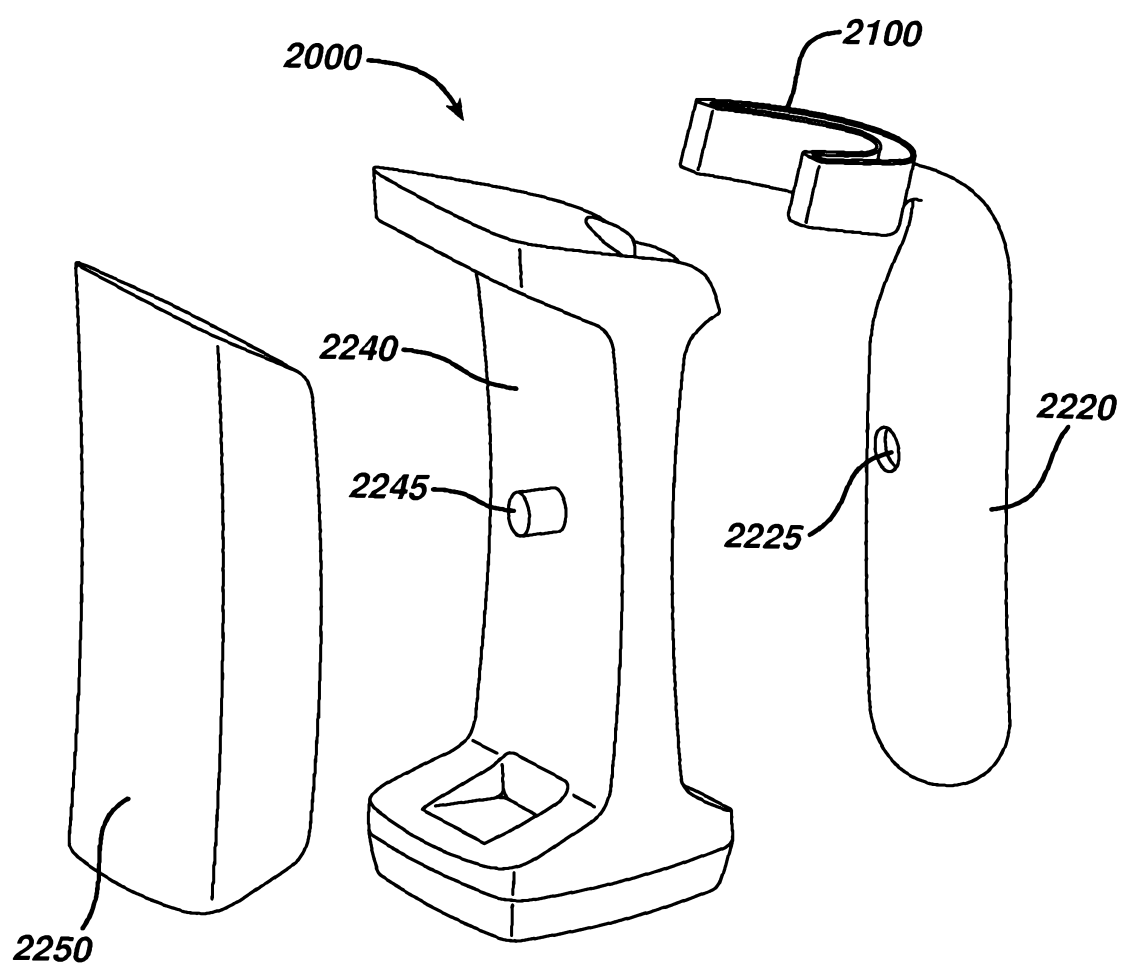


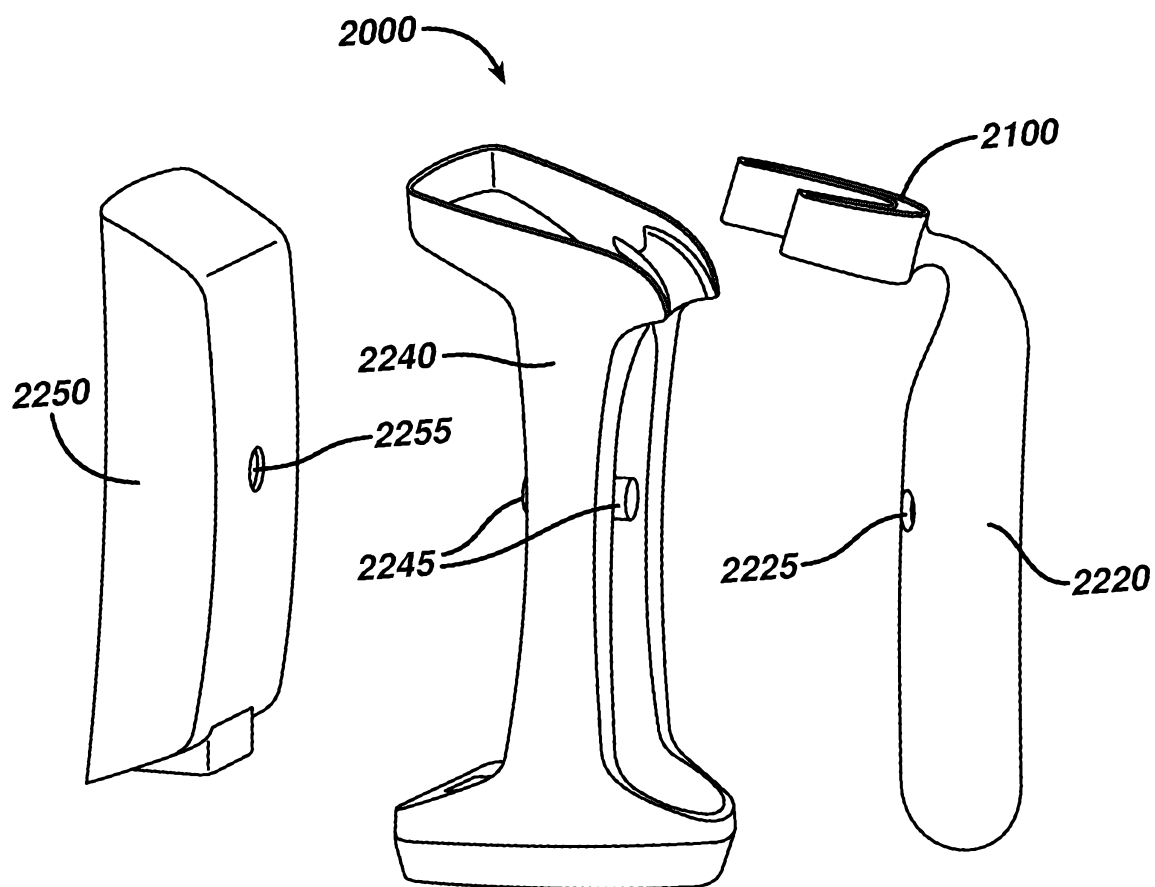
FIG. 24e

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FIG. 25a

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FIG. 25b



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FIG. 25c

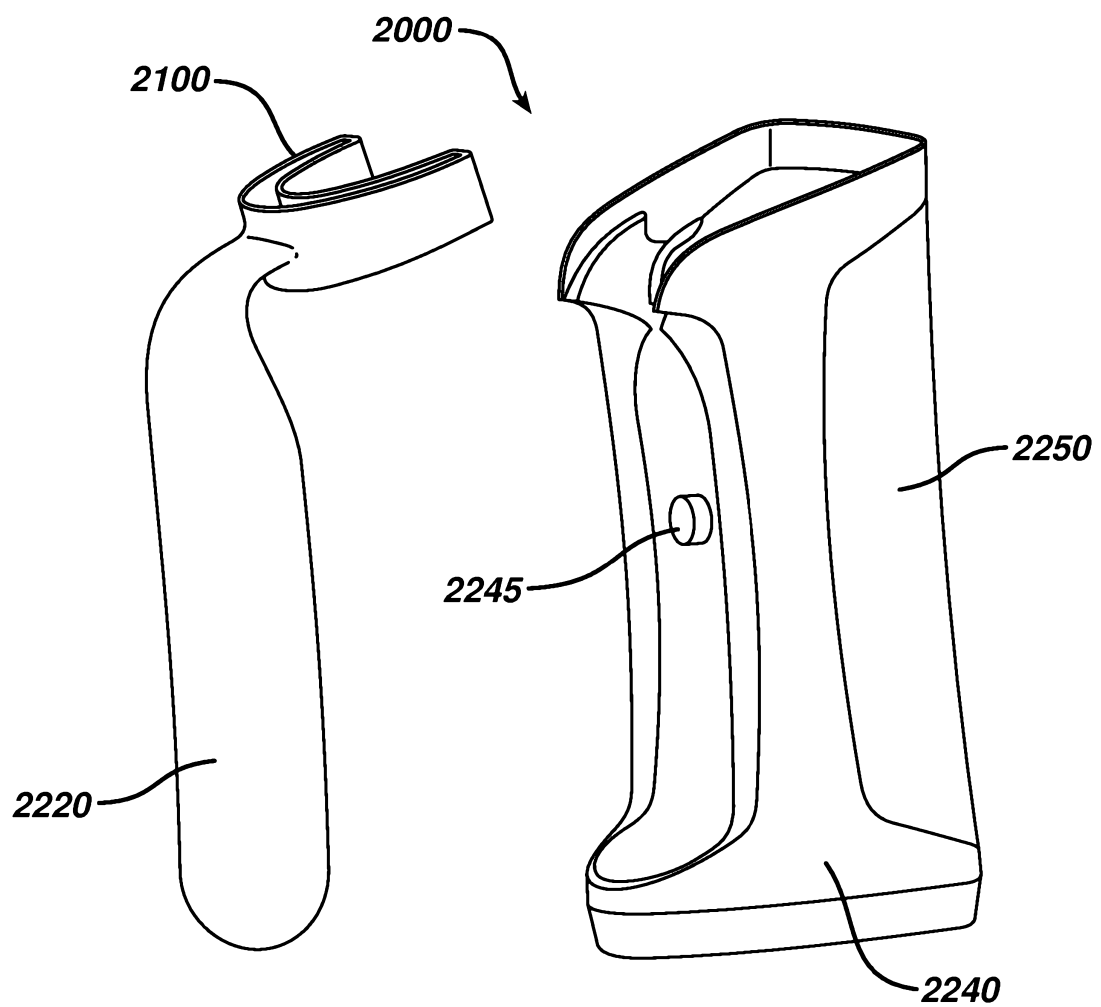


FIG. 25d

