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(54) **Title:** DROPLET DELIVERY DEVICE WITH PUSH EJECTION

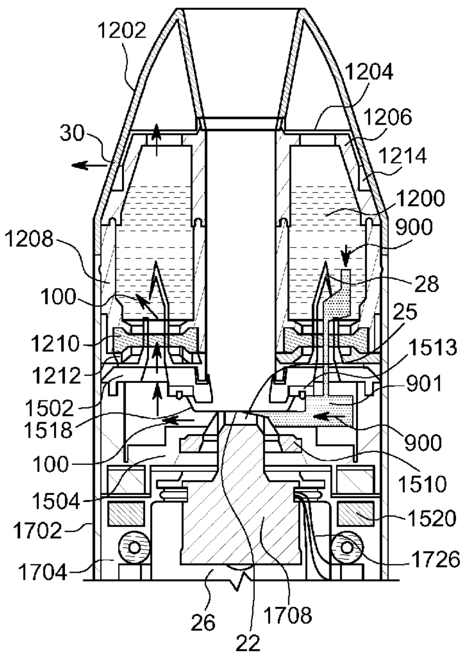

FIG. 5

(57) **Abstract:** A droplet delivery device includes a housing with a mouthpiece port or outlet from a nasal device for releasing fluid droplets, a fluid reservoir, and an ejector bracket having a membrane positioned between a mesh with a plurality of openings and a vibrating member that is coupled to an electronic transducer, such as an ultrasonic transducer. The transducer vibrates the vibrating member which causes the membrane to push fluid supplied by the reservoir through the mesh to generate droplets in an ejected stream released through the outlet.

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DROPLET DELIVERY DEVICE WITH PUSH EJECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of priority of U.S. Provisional Patent Application No. 63/280,643 filed November 18, 2021, U.S. Provisional Patent Application No. 63/256,546 filed October 16, 2021, Provisional Patent Application No. 63/256,245 filed October 15, 2021, and Provisional Patent Application No. 63/213,634 filed June 22, 2021, all of which are incorporated herein by reference in their entirety.

FIELD OF THE PUSH MODE INVENTION

[0002] This disclosure relates to droplet delivery devices with ejector mechanisms and more specifically to droplet delivery devices for the delivery of fluids that are inhaled into mouth, throat nose, and/or lungs.

BACKGROUND OF THE PUSH MODE INVENTION

[0003] The use of droplet generating devices for the delivery of substances to the respiratory system is an area of large interest. A major challenge is providing a device that delivers an accurate, consistent, and verifiable amount of substance, with a droplet size that is suitable for successful delivery of substance to the targeted area of the respiratory system.

[0004] Currently most inhaler type systems, such as metered dose inhalers (MDI), pressurized metered dose inhalers (p-MDI), or pneumatic and ultrasonic-driven devices, generally produce droplets with high velocities and a wide range of droplet sizes including large droplets that have high momentum and kinetic energy. Droplet plumes with large size distributions and high momentum do not reach a targeted area in the respiratory system, but rather are deposited throughout the pulmonary passageways, mouth, and throat. Such non-targeted deposition may be undesirable for many reasons, including improper dosing and unwanted side effects.

[0005] Droplet plumes generated from current droplet delivery systems, as a result of their high ejection velocities and the rapid expansion of the substance carrying propellant, may also lead to localized cooling and subsequent condensation, deposition and crystallization of substance onto device surfaces. Blockage of device surfaces by deposited substance residue is also problematic.

[0006] Further, conventional droplet delivery devices for delivery of nicotine, including vape pens and the like, typically require fluids that are inhaled to be heated to temperatures that negatively affect the liquid being aerosolized. Specifically, such levels of heating can produce undesirable and toxic byproducts as has been documented in the news and literature.

[0007] Accordingly, there is a need for an improved droplet delivery device that delivers droplets of a suitable size range, avoids surface fluid deposition and blockage of apertures, avoids producing undesired chemical byproducts through heating, and in an amount that is consistent and reproducible.

SUMMARY OF THE PUSH MODE INVENTION

[0008] In one embodiment of the push mode invention, a “push mode” droplet delivery device does not include a heating requirement that could result in undesirable byproducts and comprises: a container assembly with an mouthpiece port; a reservoir disposed within or in fluid communication with the container assembly to supply a volume of fluid, an ejector bracket in fluid communication with the reservoir, the ejector bracket including a mesh with a membrane operably coupled to an electronic transducer with the membrane between the transducer and the mesh, wherein the mesh includes a plurality of openings formed through the mesh’s thickness, and wherein the transducer is coupled to a power source and is operable to oscillate the membrane and generate an ejected stream of droplets through the mesh, and an ejection channel within the container assembly configured to direct the ejected stream of droplets from the mesh to the outlet. The vibrating membrane “pushing” liquid through the mesh is referred to herein as “push mode” ejection and devices in embodiments of the push mode invention may be referred to as push mode devices.

[0009] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes an ultrasonic transducer as an electronic transducer, and preferably an ultrasonic transducer that includes piezoelectric material.

[0010] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the container assembly having a fluid reservoir.

[0011] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes an ejector bracket configured for releasably coupling to the container assembly and the ejector bracket further configured for releasable coupling to an enclosure system including an electronic transducer and a power source.

[0012] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes magnets configured to releasably couple the ejector bracket and enclosure system.

[0013] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a snap mechanism and/or magnets configured to releasably couple the ejector bracket and the container assembly.

[0014] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a fluid reservoir with a self-sealing mating mechanism configured to couple to a fluid release mating mechanism of the ejector bracket.

[0015] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a fluid release mating mechanism that has a fluid conduit configured for insertion into the self-sealing mating mechanism. In a preferred embodiment, a fluid release mating mechanism includes a spike-shaped structure with a hollow interior configured to provide fluid communication between the reservoir and the membrane.

[0016] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh is configured so that the membrane does not contact the mesh and pushes fluid to be ejected as droplets from the droplet delivery device through openings in the mesh.

[0017] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the membrane having a slanted upper surface configured to contact fluid supplied from the reservoir.

[0018] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a vibrating member having a slanted tip contacting an opposite underlying surface of a slanted upper surface of the membrane.

[0019] In further embodiments of the push mode invention, an electronic transducer includes piezoelectric material that is coupled to a vibrating member with a ring-shaped beveled tip, rod-shaped beveled tip, rod-shaped tip, or a ring-shaped non-beveled tip.

[0020] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a mesh with a bottom surface in a parallel configuration with an upper surface of the membrane.

[0021] In another embodiment of the push mode invention, a droplet delivery device having membrane that cooperates with a mesh further includes the mesh including a bottom surface in a non-parallel, i.e., slanted at an angle, configuration with an upper surface of the membrane.

[0022] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a central axis of the droplet delivery device passing through the ejection channel and the membrane, and wherein the transducer is coupled to a vibrating member that is coupled to the membrane at a position offset from the central axis.

[0023] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a fluid in the reservoir including at least one of a non-therapeutic substance, nicotine, or cannabinoid.

[0024] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a fluid in the reservoir including a therapeutic substance that treats or prevents a disease or injury condition.

[0025] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a laminar flow element positioned in an ejection channel of a container assembly before a mouthpiece port of the delivery device. In preferable embodiments, the laminar flow element includes a plurality of cellular apertures. In some embodiments, a laminar flow element includes blade-shaped walls defining the plurality of cellular apertures. In further embodiments, one or more of the plurality of cellular apertures include a triangular prismatic shape, quadrangular prismatic shape, pentagonal prismatic shape, hexagonal prismatic shape, heptagonal prismatic shape, or octagonal prismatic shape.

[0026] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a breath-actuated sensor, such as a pressure sensor, operatively coupled to the power source, wherein the breath-actuated senor is configured to activate the electronic transducer upon sensing a predetermined pressure change within the ejection channel or within a passageway of the droplet delivery device in fluid communication with the ejection channel.

[0027] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the mesh made of a material of at least one of palladium nickel, polytetrafluoroethylene, and polyimide.

[0028] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the mesh made of a material of at least one of poly ether ketone, polyetherimide, polyvinylidine fluoride, ultra-high molecular weight polyethylene, Ni, NiCo, Pd, Pt, NiPd, and metal alloys.

[0029] In other embodiments a mesh may be made of single crystalline or poly crystalline materials such as silicon, silicon carbide, aluminum nitride or germanium with hole structures formed using semiconductor processes such as photo lithography and isotropic and anisotropic etching. With photolithography and isotropic and/or anisotropic etches different hole shapes can be formed in a single crystalline wafer with very high precision. Using sputtering, films can be deposited on the surface with different contact angles. Thin layers formed or deposited on the surface will have, in certain embodiments, much better adherence than film deposited on metal mesh formed by galvanic deposition or polymer mesh formed by laser ablation. This better adherence is because the surfaces on the single crystalline wafers "slices" are atomically smooth and can be etched to produce exact surface roughness to facilitate mechanical bonding with glue or other materials. Silicon carbide would be a preferable material because of its high strength and toughness. An important advantage of using semiconductor processes to fabricate hole structures from a single crystalline wafer "slice" in a mesh of embodiment of the push mode invention is that the holes and surface contact angles will be exact without the variation we see in conventional ejector plates using mesh made from galvanic deposition or laser ablation.

[0030] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the membrane made a of material of at least one of polyethylene naphthalate, polyethylenimine and poly ether ketone.

[0031] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the membrane made a of material of at least one of metal membranes, metalized polymers, threaded polymers, threaded nylon, threaded polymers that are coated with polymers or metal, threaded nylon coated with polymers or metal. threaded metals, threaded SiC, threaded graphite composites, metalized graphite composites, graphite composites coated with polymers, polymer sheets filled with carbon fibers, poly ether ketone filled with carbon fibers, polymer sheets filled with SiC fibers, polymer sheets filled with ceramic or metal fibers, ULPA filter media, Nitto Denko Temic Grade filter media, Nitto Denko polymer sheets, threaded polymers bonded to a polymer sheet, nylon weave bonded to poly ether ketone or polyimide, graphite composites bonded to polymer sheets, polymer fiber weave with metalized coating, and nylon with sputtered on Al or vapor deposited Al.

[0032] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a PZT-based ultrasonic transducer coupled to a vibrating member having a tip portion made of at least one of Grade 5 titanium alloy, Grade 23 titanium alloy, and about 99% or higher purity titanium. In certain embodiments, the vibrating member's tip includes a sputtered on outer layer of and about 99% or higher purity titanium providing a smooth tip surface configured to contact an underlying bottom surface of the membrane that is opposite an exterior top surface of the membrane positioned nearest the mesh so as to help reduce wear of the membrane and increase the longevity and operation consistency of the membrane (and also possibly vibrating member's tip portion).

[0033] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes an exterior surface of the membrane, opposite an underlying surface of the membrane contacting the vibrating member, having a hydrophobic coating.

[0034] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes an exterior surface of the membrane, opposite an underlying surface of the membrane contacting the vibrating member, having a hydrophilic coating.

[0035] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a hydrophilic coating on one or more surfaces of the mesh.

[0036] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a mesh including a hydrophobic coating on one or more surfaces of the mesh.

[0037] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a hydrophobic coating on a first surface of the mesh and a hydrophilic coating on a second surface of the mesh.

[0038] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes the membrane having an operable lifespan of over 55,000 aerosol-creating activations by the transducer.

[0039] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes at least one superhydrophobic vent in fluid communication with the reservoir that is covered with a removable aluminized polymer tab during storage.

[0040] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh further includes a removable aluminized polymer tab coupled to an exterior surface of the membrane adjacent the mesh during storage.

[0041] In another embodiment of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh includes a pre-assembly step of removing a sealed packaging including aluminum and/or aluminum coating that contains the reservoir with a fluid, preferably wherein the reservoir is included in the container assembly that is also packaged for storage in the sealed packaging. In some embodiments, sealed packaging may include dry nitrogen, argon or other gas that does not contain oxygen.

[0042] In various embodiments of the push mode invention, a droplet delivery device having a membrane that cooperates with a mesh may be used for mouth inhalation or nasal inhalation. The mouthpiece port may be sized, shaped and include materials that are better suited for that particular mouth or nasal inhalation use and purpose.

BRIEF DESCRIPTION OF THE DRAWINGS

[0043] The push mode invention will be more clearly understood from the following description given by way of example, in which:

[0044] **FIG. 1A** is an exploded view of major components of a droplet delivery device in accordance with an embodiment of the disclosure.

[0045] **FIG. 1B** is a cross-sectional view of major components of a droplet delivery device in accordance with an embodiment of the disclosure.

[0046] **FIG. 2** is a schematic view of a mesh bonded to a stainless-steel ring that supports an elastic sealing ring of a droplet delivery device in an accordance with an embodiment of the disclosure referred to as push mode II.

[0047] **FIG. 3** is a schematic view of a mesh supported by inner and outer tablet rings and an elastic sealing ring of a droplet delivery device in an accordance with an embodiment of the disclosure referred to as push mode I.

[0048] **FIG. 4** illustrates a cross-sectional view of certain dimensions of ejection and mouthpiece ports of a droplet delivery device in accordance with one embodiment of the disclosure.

[0049] **FIG. 5** illustrates a cross-sectional view of fluid flow path of a droplet delivery device with a two-part cartridge in accordance with one embodiment of the disclosure.

[0050] **FIGS. 6A and 6B** illustrate airflow of a droplet delivery device with a two-part cartridge in accordance with an embodiment of the disclosure.

[0051] **FIGS. 7A and 7B** illustrate perspective views of the disassembly of major components of a push mode I droplet delivery device (utilizing mesh support shown in FIG. 3) in an embodiment of the disclosure.

[0052] **FIG. 8** illustrates an exploded view of a push mode I droplet delivery device (utilizing mesh support shown in FIG. 3) in an embodiment of the disclosure.

[0053] **FIG. 9** illustrates isolated perspective views of COC (cyclic olefin copolymer) rings, including mesh (22), of a push mode I droplet delivery device (utilizing mesh support shown in FIG. 3) in an embodiment of the disclosure.

[0054] **FIG. 10** illustrates a schematic view of a push mode I droplet delivery device mesh suspension system (redundant to FIG. 3) in an embodiment of the disclosure.

[0055] **FIG. 11** illustrates a perspective view of lower ejector bracket including vents located on each narrow side of the bracket of a push mode I droplet delivery device (utilizing mesh support shown in FIG. 3) in an embodiment of the disclosure.

[0056] **FIGS. 12A and 12B** illustrate perspective views of the disassembly of major components of a push mode II droplet delivery device (utilizing mesh support shown in FIG. 2) in an embodiment of the disclosure.

[0057] **FIG. 13** illustrates an exploded view of a push mode II droplet delivery device (utilizing mesh support shown in FIG. 2) in an embodiment of the disclosure.

[0058] **FIG. 14** illustrates a schematic view of a push mode II droplet delivery device mesh suspension system (as also shown in FIG. 2) in an embodiment of the disclosure.

[0059] **FIG. 15** illustrates a perspective view of lower ejector bracket including vents located on each wide side of the bracket of a push mode II droplet delivery device (utilizing mesh support shown in FIG. 2) in an embodiment of the disclosure.

[0060] **FIG. 16** illustrates a lower container of a push mode II droplet delivery device (utilizing mesh support shown in FIG. 2) in an embodiment of the disclosure.

[0061] **FIG. 17** illustrates a lower container of a push mode I droplet delivery device (utilizing mesh support shown in FIG. 3) in an embodiment of the disclosure.

[0062] **FIG. 18** illustrates a perspective view of a rod tip design for a vibrating member of a droplet delivery device in accordance with one embodiment of the disclosure.

[0063] **FIG. 19** illustrates a perspective view of a ring tip design for a vibrating member of a droplet delivery device in accordance with one embodiment of the disclosure.

[0064] **FIG. 20** illustrates a cross-sectional view of single part cartridge design with a long vibrating member in a droplet delivery device in accordance with one embodiment of the disclosure.

[0065] **FIGS. 21A and 21B** illustrate cross-sectional views of single part cartridge design with a short vibrating member in a droplet delivery device in accordance with one embodiment of the disclosure.

[0066] **FIGS. 22A and 22B** illustrate cross-sectional views of single part cartridge alternative designs with a long vibrating member in a droplet delivery device in accordance with one embodiment of the disclosure.

[0067] **FIGS. 23A and 23B** illustrate cross-sectional views of single part cartridge alternative designs with a short vibrating member in a droplet delivery device in accordance with one embodiment of the disclosure.

[0068] **FIG. 24** illustrates a cross-sectional and separated view of a two-part cartridge design in a droplet delivery device in accordance with one embodiment of the disclosure.

[0069] **FIG. 25** illustrates a perspective view of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0070] **FIG. 26** illustrates an exploded view of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0071] **FIGS. 27A-27D** illustrate views of major components of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0072] **FIGS. 28A-28D** illustrate an assembly view of major components of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0073] **FIG. 29** illustrates an exploded view of a cap of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0074] **FIGS. 30A and 30B** illustrate respective front and side cross-sectional views of a fluid cartridge of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0075] **FIG. 31** illustrates a cross-sectional view of a vibrating member enclosure of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0076] **FIG. 32** illustrates a cross-sectional view of an ejector bracket adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing a mesh suspension system that follows structure and function of the mesh support shown in FIG. 14 in accordance with one embodiment of the disclosure.

[0077] **FIG. 33** illustrates a cross-sectional view of an ejector bracket adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing a mesh suspension system that follows the structure and function of the mesh support shown in FIG. 10 in accordance with one embodiment of the disclosure.

[0078] **FIGS. 34A and 34B** illustrate respective side and front cross-sectional views of a droplet delivery device adapted for pharmaceutical use (but may be other uses in other embodiments) and utilizing membrane-driven aerosolization (i.e. “push mode functionality”) having two heating elements positioned beneath a vibrating member on either side of the ejector bracket in accordance with one embodiment of the disclosure.

[0079] **FIG. 35A-35C** illustrate cross-sectional views of an airflow path for a droplet delivery device having a bottom heating element with a single part cartridge design in accordance with one embodiment of the disclosure.

[0080] **FIG. 36** illustrates cross-sectional view of a droplet delivery device having a bottom heating element and speaker with a single part cartridge design in accordance with one embodiment of the disclosure.

[0081] **FIG. 37** illustrates a cross-sectional view of an airflow path for a droplet delivery device having an inside heating element with a two-part cartridge design in accordance with one embodiment of the disclosure.

[0082] **FIG. 38** illustrates a cross-sectional view of an airflow path for a droplet delivery device having an inside heating element with a single part cartridge design in accordance with one embodiment of the disclosure.

[0083] **FIG. 39** illustrates a cross-sectional view of an airflow path for a droplet delivery device having an external heating element with a single part cartridge design in accordance with one embodiment of the disclosure.

[0084] **FIG. 40** illustrates a cross-sectional view of droplet delivery device with a heated airstream including a temperature sensor that is used in conjunction with a closed loop system to keep the temperature of the airstream constant, and also avoid overheating and user injury, in accordance with one embodiment of the disclosure.

[0085] **FIGS. 41A** and **41B** illustrate views of a droplet delivery device with adjustable air resistance via sliding sleeve and associated vent in accordance with one embodiment of the disclosure.

[0086] **FIG. 42** illustrates an elongated and narrow inhalation port of a droplet delivery device adapted for nasal inhalation and utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0087] **FIG. 43** illustrates a shorter-version inhalation port of a droplet delivery device adapted for nasal inhalation and utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0088] **FIGS. 44A and 44B** illustrate a removal cap of a droplet delivery device adapted for nasal inhalation and utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0089] **FIG. 45** illustrates a mesh with an attached plate having multiple openings for liquid to enter used in a droplet delivery device utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0090] **FIG. 46** illustrates a cross-sectional view of a capacitance cartridge having two parallel plates placed across the liquid next to the mesh-membrane area in a droplet delivery device utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0091] **FIGS. 47A-47C** illustrate a perspective view (FIG.47A), front plan view (FIG. 47B) and side plan view (FIG. 47C) of a rectangular vibrating member tip in a droplet delivery device utilizing membrane-driven aerosolization (i.e. "push mode functionality") in accordance with one embodiment of the disclosure.

[0092] **FIGS. 48A-48C** illustrate a perspective view (FIG. 48A), a perspective vibration amplitude map view (FIG. 48B) and a top vibration amplitude plan view (FIG. 48C) of an eigenmode vibrating member tip without slots or tuning and the resulting vibration amplitude maps in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0093] **FIGS. 49A-49C** illustrate a perspective view (FIG. 49A), a perspective vibration amplitude map view (FIG. 49B) and a top vibration amplitude plan view (FIG. 49C) of an eigenmode vibrating member tip with slots and the resulting vibration amplitude maps in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0094] **FIG. 50** illustrates a contoured vibrating member in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0095] **FIG. 51** illustrates a plunger vibrating member in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0096] **FIG. 52** illustrates a sensor carrier vibrating member in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0097] **FIGS. 53A and 53B** illustrate a spool vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0098] **FIGS. 54A and 54B** illustrate an optimized cylindrical vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[0099] **FIGS. 55A and 55B** illustrate an unoptimized slotted cylindrical vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[00100] **FIGS. 56A and 56B** illustrate an optimized bar vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[00101] **FIGS. 57A and 57B** illustrate an unoptimized bar vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[00102] **FIGS. 58A and 58B** illustrate a perspective view (FIG. 58A) and cross-sectional vibration amplitude view (58B) of a booster vibrating member and the resulting vibration amplitude map in a droplet delivery device utilizing membrane-driven aerosolization (i.e. “push mode functionality”) in accordance with one embodiment of the disclosure.

[00103] **FIGS. 59A-59C** illustrate a perspective view (FIG. 59A), top plan view (FIG. 59B) and front plan view (FIG. 59C) of an alternative vibrating member that couplee to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00104] **FIGS. 60A-60C** illustrate a perspective view (FIG. 60A), top plan view (FIG. 60B) and front plan view (FIG. 60C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00105] **FIGS. 61A-61C** illustrate a perspective view (FIG. 61A), top plan view (FIG. 61B) and front plan view (FIG. 61C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00106] **FIGS. 62A-62C** illustrate a perspective view (FIG. 62A), top plan view (FIG. 62B) and front plan view (FIG. 62C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00107] **FIGS. 63A-63C** illustrate a perspective view (FIG. 63A), top plan view (FIG. 63B) and front plan view (FIG. 63C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00108] **FIGS. 64A-64C** illustrate a perspective view (FIG. 64A), top plan view (FIG. 64B) and front plan view (FIG. 64C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00109] **FIGS. 65A-65D** illustrate a perspective view (FIG. 65A), top plan view (FIG. 65B), front plan view (FIG. 65C) and cross-sectional view along A-A of FIG. 65B (FIG. 65D) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00110] **FIGS. 66A-66C** illustrate a perspective view (FIG. 66A), top plan view (FIG. 66B) and front plan view (FIG. 66C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00111] **FIGS. 67A-67C** illustrate a perspective view (FIG. 67A), top plan view (FIG. 67B) and front plan view (FIG. 67C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00112] **FIGS. 68A-68D** illustrate a perspective view (FIG. 68A), top plan view (FIG. 66B), front plan view (FIG. 66C) and side plan view (66D) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00113] **FIGS. 69A and 69B** illustrate a perspective view (FIG. 69A) and side plan view (FIG. 69B) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00114] **FIGS. 70A-70C** illustrate a perspective view (FIG. 70A), top plan view (FIG. 70B) and front plan view (FIG. 70C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00115] **FIGS. 71A-71C** illustrate a perspective view (FIG. 71A), top plan view (FIG. 71B) and front plan view (FIG. 71C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00116] **FIGS. 72A-72C** illustrate a perspective view (FIG. 72A), top plan view (FIG. 72B) and front plan view (FIG. 72C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00117] **FIGS. 73A-73C** illustrate a perspective view (FIG. 73A), top plan view (FIG. 73B) and front plan view (FIG. 73C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00118] **FIGS. 74A-74C** illustrate a perspective view (FIG. 74A), top plan view (FIG. 74B) and front plan view (FIG. 74C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00119] **FIGS. 75A-75C** illustrate a perspective view (FIG. 75A), top plan view (FIG. 75B) and front plan view (FIG. 75C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00120] **FIGS. 76A-76C** illustrate a perspective view (FIG. 76A), top plan view (FIG. 76B) and front plan view (FIG. 76C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00121] **FIGS. 77A-77C** illustrate a perspective view (FIG. 77A), top plan view (FIG. 77B), front plan view (FIG. 77C) and side plan view (FIG. 77D) of an alternative vibrating

member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00122] **FIGS. 78A-78C** illustrate a perspective view (FIG. 78A), top plan view (FIG. 78B) and front plan view (FIG. 78C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00123] **FIGS. 79A-79C** illustrate a perspective view (FIG. 79A), top plan view (FIG. 79B) and front plan view (FIG. 79C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00124] **FIGS. 80A-80D** illustrate a perspective view (FIG. 80A), top plan view (FIG. 80B), front plan view (FIG. 80C) and side plan view (FIG. 80D) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00125] **FIGS. 81A-81D** illustrate a perspective view (FIG. 81A), top plan view (FIG. 81B), front plan view (FIG. 81C) and side plan view (FIG. 81D) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00126] **FIGS. 82A-82D** illustrate a perspective view (FIG. 82A), top plan view (FIG. 82B), front plan view (FIG. 82C) and side plan view (FIG. 82D) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00127] **FIGS. 83A-83C** illustrate a perspective view (FIG. 83A), top plan view (FIG. 83B) and front plan view (FIG. 83C) of an alternative vibrating member that couples to a transducer of droplet delivery devices in accordance with an embodiment of the disclosure.

[00128] **FIGS. 84A-84Q** illustrate alternative structures of laminar flow elements of a container assembly of a droplet delivery device in accordance with embodiments of the disclosure.

[00129] **FIG. 85A** illustrates an ultrasonic transducer, including a vibrating member tip portion, in a droplet delivery device in accordance with an embodiment of the disclosure.

[00130] **FIG. 85B** is a partial cross-sectional top view of the ultrasonic transducer of **FIG. 85A** coupling to a membrane in a droplet delivery device in accordance with an embodiment of the disclosure.

[00131] **FIGS. 85C and 85D** are schematic views of the ultrasonic transducer and membrane of **FIG. 85B** in droplet delivery devices in accordance with alterative embodiments

of the disclosure wherein a mesh includes first securing mechanism in **FIG. 85C** and second securing mechanism in **FIG. 85D**.

[00132] **FIG. 86A** is a partial cross-sectional top view of an ultrasonic transducer coupled to a membrane in a droplet delivery device in accordance with an embodiment of the disclosure.

[00133] **FIGS. 86B and 86C** are schematic views of the ultrasonic transducer and membrane of **FIG. 86A** in droplet delivery devices in accordance with alterative embodiments of the disclosure wherein a mesh includes first securing mechanism in **FIG. 86B** and second securing mechanism in **FIG. 86C.**

[00134] **FIG. 87** is partial cross-sectional top view of a droplet delivery device including an ultrasonic transducer with vibrating member tip portion offset from a central axis of the droplet delivery device passing through a slanted membrane and mesh in accordance with an embodiment of the disclosure.

[00135] **FIG. 88A** is a partial cross-sectional top view of an ultrasonic transducer with a non-beveled ring-shaped vibrating member tip portion coupled to a tilted mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00136] **FIG. 88B** is a schematic view of the ultrasonic transducer and membrane of **FIG. 88A** in droplet delivery devices in accordance with an embodiment of the disclosure.

[00137] **FIG. 89A** is a partial cross-sectional top view of an ultrasonic transducer with a beveled ring-shaped vibrating member tip portion coupled to a slanted membrane in a droplet delivery device in accordance with an embodiment of the disclosure.

[00138] **FIG. 89B** illustrates a slanted membrane that cooperates with an ultrasonic transducer and mesh illustrated in **FIG. 89A**.

[00139] **FIGS. 89C and 89D** are schematic views of the ultrasonic transducer and membrane of **FIG. 89A** in droplet delivery devices in accordance with alterative embodiments of the disclosure wherein a mesh includes first securing mechanism in **FIG. 89C** and second securing mechanism in **FIG. 89D.**

[00140] **FIG. 89E** illustrates an ultrasonic transducer with a beveled ring-shaped vibrating member tip portion of **FIG. 89A**.

[00141] **FIG. 90A** is a partial cross-sectional top view of an ultrasonic transducer with a non-beveled ring-shaped vibrating member tip portion coupled to a membrane and touching the mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00142] **FIG. 90B** is a schematic view of the ultrasonic transducer and membrane of **FIG. 90A** in droplet delivery devices in accordance with an embodiment of the disclosure. This embodiment can be used with a mesh carrier either of push mode I or II.

[00143] **FIG. 91A** is a partial cross-sectional top view of an ultrasonic transducer with a beveled ring-shaped vibrating member tip portion coupled to a slanted membrane with a space between the mesh and membrane in a droplet delivery device in accordance with an embodiment of the disclosure.

[00144] **FIG. 91B** is a schematic view of the ultrasonic transducer and membrane of **FIG. 91A** in droplet delivery devices in accordance with an embodiment of the disclosure. This embodiment can be used with a mesh carrier of either push mode I or II.

[00145] **FIG. 92** is schematic view of an ultrasonic transducer with a non-beveled ring-shaped vibrating member tip portion coupled to a membrane with a space between the mesh and membrane in a droplet delivery device in accordance with an embodiment of the disclosure. This embodiment can be used with a mesh carrier of either push mode I or II.

[00146] **FIGS. 93A and 93B** are schematic views of an ultrasonic transducer of a droplet delivery device with an isolation view (FIG. 93A) and a cross-sectional view along line A-A of FIG. 93A (FIG. 93B) of the ultrasonic transducer having a wide and flat vibrating member tip portion together with membrane and mesh in accordance with an embodiment of the disclosure.

[00147] **FIGS. 94A-94D** are schematic views of a droplet delivery device (FIG. 94) with a cross-sectional isolation views of the ultrasonic transducer along line B-B of FIG. 94A (FIG. 94B), an isolation view (FIG. 94C) and a cross-section view along line A-A of FIG. 94C (FIG. 94D) of the ultrasonic transducer having a wide and ring-shaped tip portion together with membrane and mesh in accordance with an embodiment of the disclosure.

[00148] **FIG. 95** is a schematic block illustration of an aluminized polymer tab in an embodiment of the disclosure.

[00149] **FIGS. 96A-96D** are perspective views of a membrane of a droplet delivery device in accordance with an embodiment of the disclosure.

[00150] **FIGS. 97A and 97B** illustrate a cross-sectional view (FIG. 97A) and a zoomed view (FIG. 97B) of a polymer mesh supported in a raised position by a stainless-steel annulus with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00151] **FIGS. 98A and 98B** illustrate a cross-sectional view (FIG. 98A) and a zoomed view (FIG. 98B) of a polymer mesh supported in a lowered position by a stainless-steel annulus

with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00152] **FIGS. 99A and 99B** illustrate a cross-sectional view (FIG. 99A) and a zoomed view (FIG. 99B) of a polymer mesh supported in a raised position by a first stainless-steel annulus and having a second stainless steel annulus as a reinforcement coupled, such as by bonding with glue or adhesive, on top of the first annulus with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00153] **FIGS. 100A and 100B** illustrate a cross-sectional view (FIG. 100A) and a zoomed view (FIG. 100B) of a polymer mesh supported in a lowered position by a first stainless-steel annulus and having a second stainless steel annulus as a reinforcement coupled, such as by bonding with glue or adhesive, below the first annulus with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00154] **FIGS. 101A-101C** illustrate cross-sectional views of a polymer mesh supported in a raised position (FIG. 101A), lowered position (FIG. 101B) and via jagged support (FIG. 101C) with plastic elements of a ring-like support (and without a metal annulus) with respect to membranes and transducer coupled to a vibrating member in droplet delivery devices in accordance with embodiments of the disclosure.

[00155] **FIGS. 102A-C** illustrate zoomed views of FIG. 101A (FIG. 102A), FIG. 101B (FIG. 102B) and FIG. 101C (FIG. 102C).

[00156] **FIG. 103A and 103B** illustrate a cross-sectional view (FIG. 103A) and a zoomed view (FIG. 103B) of a polymer mesh and stainless-steel capillary plate having openings in the plate and the plate underlying the polymer mesh between a membrane covering a vibrating member tip portion and the mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00157] **FIG. 103C** is a schematic top plan view of a polymer mesh illustrated in FIGS. 103A and 103B.

[00158] **FIG. 103D** is a schematic top plan view of a stainless-steel capillary plate illustrated in FIGS. 103A and 103B.

[00159] **FIG. 104** illustrates a schematic view of a polymer mesh and capillary plate wherein the capillary plate is made of PEN material like the membrane covering the vibrating member (also made of PEN material) and further including a spacer (such as metal, ceramics or plastic) between the capillary plate and the mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00160] **FIGS. 105A and 105B** illustrate a cross-sectional view (FIG. 105A) and zoomed view (FIG. 105B) of a polymer mesh with a plastic or silicone ring-shaped type bracket (d) coupled to a stainless steel annulus shaped downward and then up toward a center portion of the annulus that couples to a polymer mesh with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00161] **FIGS. 106A and 106B** illustrats a cross-sectional view (FIG. 106A) and zoomed view (FIG. 106B) of a polymer mesh with a plastic or silicone ring-shaped type bracket center portion of the annulus that couples to a polymer mesh with respect to a membrane and transducer coupled to a vibrating member having a tip portion in a droplet delivery device in accordance with an embodiment of the disclosure.

[00162] **FIGS. 107A-107B** illustrate cross-sectional views of a polymer mesh with a plastic or silicone ring-shaped type bracket coupled to double-reinforced stainless-steel annuluses (similar to FIGS. 99 and 100) wherein the polymer mesh is raised with further extending top reinforcement (FIG. 107A), the polymer mesh is raised with extending top reinforcement (FIG. 107B), the polymer mesh is lowered with extending underlying reinforcement (FIG. 107C), the polymer mesh is lowered with further extending underlying reinforcement (FIG. 107D) with respect to membrane and transducer coupled to a vibrating member having a tip portion in droplet delivery devices in accordance with embodiments of the disclosure.

[00163] **FIGS. 108A-108D** illustrats zoomed views of FIG. 107A (FIG. 108A), FIG. 107B (FIG. 108B), FIG. 107C (FIG. 108C) and FIG. 107D (FIG. 108D).

[00164] **FIGS. 109A-109D** illustrate a cross-sectional view (FIG. 109A), a perspective view (FIG. 109B), a top plan view (FIG. 109C) and a cross-sectional zoomed view along line C-C of FIG. 109C (FIG. 109D) of a crystalline silicon or silicon carbide “wafer”-type mesh between ring-structured supports and processed with semiconductor technology to provide exact fabrication of smooth openings, such as pseudospherical, (zoomed cross-sectional view of FIG. 109D intended to show openings fully through mesh), in the mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00165] **FIG. 110** illustrates a cross-sectional and zoomed view of a crystalline silicon or silicon carbide “wafer”-type mesh with well-type openings that begin larger though the thickness of the mesh and then terminate or are finished with smaller apertures in the openings (and which also may be angled with semiconductor technology processing) in the mesh in a droplet delivery device in accordance with an embodiment of the disclosure.

[00166] **FIGS. 111A-111C** illustrate a perspective view of a first end of absorber and baffle with fins (FIG. 111A), a perspective view of a second opposite end of a baffle with fins (FIG. 111B) and a cross-sectional, partial schematic view a droplet delivery device airway and ejector plate with mesh including a baffle with fins in accordance with an embodiment of the disclosure.

[00167] **FIG. 112** is a streamline velocity field graphical map of an airflow path of a droplet delivery device including airflow directors without a baffle in accordance with an embodiment of the disclosure.

[00168] **FIG. 113** is a streamline velocity field graphical map of an airflow path of a droplet delivery device including a baffle with wicking material and no airflow directors in accordance with an embodiment of the disclosure.

[00169] **FIG. 114** is a streamline velocity field graphical map of an airflow path of a droplet delivery device including a baffle with wicking material and also including airflow directors in accordance with an embodiment of the disclosure.

DETAILED DESCRIPTION

[00170] Push Mode Overview

[00171] Push mode has been developed as a reduced-risk product to deliver (i) nicotine, cannabinoids, and other non-therapeutic substances (devices described herein as “BlueSky” are preferable for use with such substances), as well as (ii) therapeutic and prescriptive drug products (devices described herein as “Norway” are preferable for use with such products). The push mode device is designed to deliver the user a safe and controlled dose. The push mode droplet delivery device 10 is capable of delivering aqueous and nonaqueous solutions and suspensions at room temperature. Large molecule formulations, whether water soluble or not, can also be delivered with this technology. Harmful chemical by-products commonly found with heated nicotine, and other substances, are eliminated in the push mode device making it a safer option for aerosol delivery.

[00172] Push mode utilizes a vibrating member 1708 and transducer 26 that work in conjunction with a membrane 25 and mesh 2 to aerosolize fluid 901, which is held in a reservoir 1200 and supplied to the mesh 22 using various methods (e.g., wick material, hydrophilic coatings, capillary action, etc.). Preferably the vibrating member is coupled to the transducer, such as by bonding (e.g. adhesives and the like), welding, gluing, physical connections (e.g.

brackets and other mechanical connectors), and the like. The transducer and vibrating member interact with the membrane to push fluid through the mesh. As illustrated and described in various embodiments, the membrane may in some cases contact the mesh while also “pushing” fluid through holes in the mesh, and may in other cases be separated without contacting the mesh to push liquid through holes in the mesh. The transducer may comprise one or more of a variety of materials (e.g., PZT, etc.). In certain embodiments the transducer is made of lead-free piezoelectric materials to avoid creation of unwanted or toxic materials in a droplet delivery device intended for human inhalation. The vibrating member may be made of one or more of a variety of different materials (e.g., titanium, etc.). The mesh may be one or more of a variety of materials (e.g., palladium nickel, polyimide, etc.). After the fluid is pushed through the mesh, a droplet spray is formed and ejected through a mouthpiece port, carried by entrained air.

[00173] The device is tunable and precise. The device can be optimized for individual user preferences or needs. The aerosol mass ejection and mass median aerodynamic diameter (MMAD) can be tuned to desired parameters via the mesh hole size, mesh treatment, membrane design, vibrating member design, airflow, manipulation of power to the transducer, etc. The design produces an aerosol comprised of droplets with a high respirable fraction, such that the lungs can absorb the aerosol most efficiently.

[00174] The vibrating member and transducer are both separate from the cartridge, isolated by the membrane. Not only does this create a safer product, but it eases manufacturability. The vibrating member and transducer are both typically expensive components. Keeping these components in the enclosure system rather than the cartridge reduces the cost of goods sold (COGS).

[00175] Element Number Tables

[00176] Substance, feature, and part numbers are provided for convenient reference with respect to the descriptions and figures provided herein in Table 1:

[00177] Table 1: Element Numbers

Substance Number	Substance Name
100	Airflow
800	Air
900	Fluid flow
901	Fluid

[00178]

Feature Number	Feature Name
10	Droplet delivery device
12	Container assembly

15	Ejector bracket
17	Enclosure system
20	Airflow outlet
24	Airflow inlet
26	Heat exchange area
28	Spike
30	Air exchange outlet
40	Mouthpiece Port
41	Nasal Inhalation Port
42	Ejection Port
43	Nasal Inhalation Cap
45	Mesh plate with holes
47	Mesh and mesh plate spacer
170	Vibrating member tip
220	Central Axis
230	Vibrating member central axis
1200	Fluid reservoir
2200	Fluid reservoir
2250	Spiral

[00179]

Part Number	**Part Name**	**Material**	**Embodiment Push Mode I and/or II**
22	Mesh	Palladium nickel	I and II
25	Membrane	Various Material	I and II
26	Transducer	PZT, lead-free material	I and II
1200's	**BlueSky Container**		
1202	Mouthpiece	COC	I and II
1204	Vent material	Sintered PTFE – PMA20	I and II
1206	Upper container	COC	I and II
1208	Middle container	COC	I and II
1210	Septum	Butyl rubber	I and II
1212	Lower container	COC	I
1213	Extended lower container	COC	II
1214	Container ring	COC	I and II
1500's	**BlueSky Ejector Bracket**		
1502	Upper ejector bracket	COC	I and II
1504	Lower ejector bracket	COC	I and II
1506	Upper mesh carrier	COC	I
1508	Lower mesh carrier	COC	I
1510	Membrane holder	COC	I and II
1512	Suspension gasket	Silicone	I
1513	Carrier gasket	Silicone	II
1518	Stainless steel mesh carrier	SUS316L	II
1519	Wick		I and II
1520	Magnet	N54 Ni coating	I and II

1522	Carrier O-Ring	Silicone	II
1524	Small O-Ring	Silicone	Simplified cartridge
1526	Large O-Ring	Silicone	Simplified cartridge
1528	Parallel plate capacitor		
1600	Laminar flow element	COC	I and II
1700's	**BlueSky Enclosure System**		
1702	Enclosure	Aluminum 6063 alloy	I and II
1704	Vibrating member front cover	PC/ABS	I and II
1706	Vibrating member rear cover	PC/ABS	I and II
1708	Vibrating member	Titanium alloy	I and II
1710	Transducer contact pin	Brass 3604 alloy, gold-plated	I and II
1712	Fingerprint/button/sealing bracket	PC/ABS	I and II
1714	Fingerprint/button cover	PC/ABS	I and II
1716	Enclosure rear cover	PC/ABS	I and II
1718	Enclosure sealing ring	Silicone	I and II
1720	Sensor director	Silicone	I and II
1722	Fingerprint/button	PC/ABS	I and II
1725	PCB	Many materials	All
1726	Spring electrode	SUS304	All
1728	USB-C port	PC/ABS	All
1730	Battery/Power supply	Li-Ion	Heater-Beluga
1732	Airflow Sleeve	PC/ABS	Air resistance
1734	Speaker		Speaker-Beluga
1760	Nodal-mounted sensing device		
1762	Sensor control unit		
1900's	**Heating Components**		
1902	Heating element	Nichrome 80	Heater
1904	Heat insulation		Heater
1906	Airflow accelerator		
1908	Electrode		All
1910	Temperature Sensor		Heater
2200's	**Norway Ejector Bracket and Container**		
2201	Mouthpiece	COC	Norway D
2202	Faceplate	SUS316L	Norway D
2203	Ejector Bracket Bottom Cover	COC	Norway D
2204	Ejector Bracket ID Chip	Many Materials	Norway D
2205	Ejector Bracket	COC	Norway D
2206	O-Ring	Silicon	All
2207	Mesh		Norway D
2208	Membrane Carrier	COC	Norway D
2209	Membrane		Norway D
2210	Cartridge Spacer	COC	Norway D

2211	Septum Cap	COC	Norway D
2212	Septum	Butyl Rubber	Norway D
2213	Lower Container	COC	Norway D
2214	Vent Material		Norway D
2215	Upper Container	COC	Norway D
2216	Vent Spacer		Norway D
2217	Mesh Carrier		
2218	Suspension gasket		
2219	Carrier gasket		
2220	Upper mesh carrier	COC	
2221	Lower mesh carrier	COC	
2222	Stainless steel mesh carrier	SUS316L	
2400's	**Norway Face Seal**		
2401	Screw		Norway D
2402	Cartridge Sealer Top Piece		Norway D
2403	O-Ring	Silicon	Norway D
2404	Cartridge Sealer Middle Piece		Norway D
2405	Screw		Norway D
2406	Cartridge Sealer Bottom Piece		Norway D
2407	Cap Spring	Steel Alloy	Norway D
2408	Screw		Norway D
2409	Device Cap	COC	Norway D
2410	Screw		Norway D
2411	Pin Screw	COC	Norway D
2412	Magnet		All
2600's	**Norway Vibrating Member Components**		
2601	Vibrating Member Enclosure	Aluminum Alloy	Norway D
2602	Vibrating Member Front Cover	COC	Norway D
2603	Vibrating Member and Transducer Assembly	Titanium Alloy and PZT4	Norway D
2604	Vibrating Member Rear Cover	COC	Norway D
2605	Vibrating Member Cover Front Holder	Silicon	Norway D
2606	Vibrating member assembly Spring	Steel Alloy	Norway D
2607	Vibrating Member Device Bracket	COC	Norway D
2608	Vibrating Member Cover Rear Holder		
2609	Screw		
2800's	**Norway Enclosure System**		
2801	Device Cap Release Axel		Norway D
2802	Cartridge Release Button Cover		Norway D

2803	Cartridge Release Button Actuator		Norway D
2804	Spacer		Norway D
2805	Cartridge Release Spring		Norway D
2806	7-Seg Display		Norway D
2807	Device Battery Cover Release		Norway D
2808	Device Battery Cover Release Spring		Norway D
2809	Device Battery Cover Axel		Norway D
2810	Device Enclosure Gasket		Norway D
2811	Device Bottom Enclosure		Norway D
2812	AAA Batteries		Norway D
2813	Device Battery Cover Gasket		Norway D
2814	Device Battery Cover		Norway D
2815	LED Display Cover		Norway D
2816	Device Front Cover Buttons		Norway D
2817	7-Seg Display Cover		Norway D
2818	Device Top Enclosure		Norway D
2819	Device Cap Release		Norway D
3300	Aluminized polymer tab		
4000	Baffle		
4050	Baffle fin		
4100	Absorbent Plug		

[00180] "BlueSky" Embodiments

[00181] Referring to FIGS. 1A and 1B, a BlueSky push mode device 10 includes main components of container assembly 12, ejector bracket 15 and enclosure system 17. Currently, two embodiments of BlueSky push mode, I and II, have been prototyped and tested. Referring to FIG. 2, inclusion of a mesh supported by a stainless-steel ring and elastic sealing ring in a droplet delivery device 10 is referred to as "push mode II" herein. Referring to FIG. 3 inclusion of a mesh supported by upper and lower mesh carrier and an elastic sealing ring in a droplet delivery device 10 is referred to as "push mode I" herein.

[00182] The push mode I and II embodiments have a transducer consisting of a lead zirconate titanate (PZT) disc bonded to the bottom of a vibrating member made of titanium alloy. The vibrating member and transducer are encased by a plastic cover in an enclosure system 17. A membrane made of polyethylene naphthalate (PEN) in the ejector bracket 15 isolates the transducer and vibrating member from the fluid that is supplied from a reservoir in the container assembly 12. The membrane can be thermoformed to the shape of the vibrating member tip. The embedded system on the device consists of the transducer, pressure sensor, and lithium-ion battery all connected on a single board microcontroller. The aluminum enclosure that houses the embedded system contains a button that can double as a fingerprint sensor for use with controlled substances. The device is charged through a USB-C charging port. Magnets are used to hold the cartridge in the enclosure.

[00183] Embodiments use a two-component cartridge system to keep the fluid from contacting the mesh in storage. This design involves two spikes, one of which contains wicking material, on one part of the cartridge, the ejector bracket. The other part of the cartridge, the container, houses a fluid reservoir and two septa. The user pushes the ejector bracket and container together, and the spikes puncture the septa, creating a path for fluid to flow to the mesh. The wicking material in one spike aids in the supply of fluid to the mesh. The other spike, which does not include wicking material, allows air to enter the container for pressure equalization. Vents covered with vent material are located at the top of each side of the fluid reservoir and are connected to the open atmosphere via airflow outlets, allowing for equalization of pressure.

[00184] Referring to FIG. 4, there is an ejection port 42 with a length of 25mm and a mouthpiece port with a length of 10mm. The preferred length of the ejection port is 0mm-50mm. The preferred mouthpiece port length is 0mm-50mm. FIG. 5 shows the fluid 900 and ventilation 100 flow paths through the spikes 28 in prototyped embodiments. FIGS. 6A and 6B show the entrained air path of prototyped embodiments.

[00185] BlueSky I push mode

[00186] FIGS. 7A and 7B show a rendering and a CAD overview, respectively, of the push mode I embodiment. The overviews in FIGS. 7A and 7B show the container assembly 12, ejector bracket 15, and the enclosure system 17, from left to right.

[00187] FIG. 8 provides an exploded view of the components from the push mode I embodiment.

[00188] Referring to FIG. 9, the push mode I embodiment includes a mesh carrier that includes two COC rings 1506, 1508 that are ultrasonically welded holding the mesh 22 and suspension gasket 1512. The COC rings sandwich the mesh and suspension gasket as shown in FIG. 10. The gasket is placed between the upper and lower ejector brackets.

[00189] Referring to FIG. 11, two vents are located on the narrow sides of the lower ejector bracket 1504 in the push mode I embodiment. The spikes are located on the upper ejector bracket 1502. The container, which houses the fluid reservoir 1200, includes three COC pieces. The two septa 1210 are held between the middle and lower container pieces. A container ring is bonded onto the upper 1206 and middle 1208 container pieces and the mouthpiece 1202 snaps onto the upper container piece 1206.

[00190] BlueSky II push mode

[00191] FIGS. 12A and 12B show a rendering and a diagrammatic overview of the push mode II embodiment, respectively. The overviews in FIGS. 12A and 12B show the container assembly 12, ejector bracket 15, and the enclosure assembly 17, from left to right.

[00192] FIG. 13 illustrates an exploded view of the components of the push mode II embodiment.

[00193] In the push mode II embodiment, a stainless-steel annulus carrier 1518 is bonded to the mesh 22. A gasket 1513 is placed above the mesh and mesh carrier between the upper 1502 and lower 1504 ejector brackets. FIG. 14 illustrates the push mode II embodiment mesh carrier 1518 and gasket 1513.

[00194] Two vents are located on the wide sides of the lower ejector bracket 1504 as shown in FIG. 15. The spikes are located on the upper ejector bracket 1502.

[00195] As in push mode I, the container, which houses the fluid reservoir, includes three COC pieces. The lower container for the push mode II embodiment extends further than in push mode I, with the tubular portion extending into the upper ejector bracket.

[00196] FIG. 16 (push mode II) and FIG. 17 (push mode I) illustrate a comparison of the lower containers of each embodiment. The extension is necessary because the mesh sits lower, compared to I, due to the stainless-steel mesh carrier being thinner than the COC carrier of I. The two septa are held between the middle and lower containers. A container ring is bonded onto the upper and middle container pieces and the mouthpiece snaps onto the upper container piece.

[00197] BlueSky Vibrating Member and Membranes

[00198] Push mode has multiple vibrating member and membrane designs. Table 2 and Table 3 contain descriptions of the vibrating member and membrane designs, respectively, that have been prototyped and tested. Referring to FIGS. 18 and 19, there are currently two different tips for the vibrating member rod tip and ring tip, respectively.

[00199] Table 2: Description of vibrating members

Vibrating Member	Description
H1	1.0mm diameter rod tip
H2	1.5mm diameter rod tip
H3	2.0mm diameter rod tip
H4	3.5mm diameter rod tip
H5	3.5mm diameter ring tip with a 2-degree tilt
H6	3.5mm diameter ring tip with a 5-degree tilt
H7	3.5mm diameter ring tip with an 8-degree tilt
H8	3.5mm diameter ring tip with no tilt

H9	3.5mm diameter rod tip with 3-degree tilt

[00200] Table 3: Description of membranes

Membrane Style	Description
M1	Thermoformed to a 1.0mm diameter circle with a round plateau, used with H1
M2	Thermoformed to a 1.0mm diameter circle with a 2-degree tilt, used with H1
M3	Thermoformed to a 1.0mm diameter circle with a 5-degree tilt, used with H1
M4	Thermoformed to a 1.0mm diameter circle with an 8-degree tilt, used with H1
M5	Thermoformed to a 1.5mm diameter circle with a 2-degree tilt, used with H2
M6	Thermoformed to a 1.5mm diameter circle with a 5-degree tilt, used with H2
M7	Thermoformed to a 1.5mm diameter circle with an 8-degree tilt, used with H2
M8	Thermoformed to a 2.0mm diameter circle with a 2-degree tilt, used with H3
M9	Thermoformed to a 2.0mm diameter circle with a 5-degree tilt, used with H3
M10	Thermoformed to a 2.0mm diameter circle with an 8-degree tilt, used with H3
M11	Thermoformed to a 3.5mm diameter circle with a round plateau, used with H4
M12	Thermoformed to a 3.5mm diameter circle with a 2-degree tilt, used with H5
M13	Thermoformed to a 3.5mm diameter circle with a 5-degree tilt, used with H6
M14	Thermoformed to a 3.5mm diameter circle with an 8-degree tilt, used with H7
M15	Thermoformed to a 3.5mm diameter circle with no tilt, used with H4 or H8

[00201] The transducer requires a large amount of power during the actuation of the device. As the power usage increases, the heat generated by the printed circuit board assembly (PCBA) increases. The effect from the heat is mitigated through several design features in the PCBA. A four-layer PCBA increases anti-interference and heat dissipation capabilities. The PCBA also contains a large amount of copper foil, making it conducive to heat dissipation. The MOSFET driving the transducer adopts a high-current package to avoid damage caused by heating in long-term continuous operation. The automatic transformer, to increase the voltage output, it is suspended to insulate it from the rest of PCBA. These features allow the device to operate for days without concern of overheating or being subjected to electrical noise.

[00202] BlueSky Life Testing

[00203] The prototype BlueSky push mode embodiments, I and II, have gone through life testing. The life test consisted of repeated three-second dosing with one-second resting intervals over the course of several days. Mass ejection was done before and after the life test. Mass ejection is defined as the mass the device aerosolizes over one three-second dose. Mass ejection data before the life test is listed in Table 3 and the data for after life testing is listed in Table 4. The mass ejection of one embodiment remained consistent before and after 55,000 doses and can likely go beyond. This embodiment, II push mode with H4 and M11, has a stainless-steel mesh carrier. There is a second embodiment, I push mode, which has a COC plastic mesh carrier. Due to heat from the extreme dosing cycling, the plastic mesh carrier warped during testing. This led to a decrease in mass ejection after the life test. However, the stainless-steel carrier in II push mode did not warp from the heat, which allowed it to remain consistent after testing. In both I and II, thermal management is improved through a four-layer PCBA, a larger than standard amount of copper foil, and a high current MOSFET driver. The conditions of the testing are not representative of normal consumer use. During normal daily use, where extreme heating does not occur, both embodiments, I and II, show consistent mass ejection. Tables 2 and 3 provide details of the referenced Vibrating Member and Membrane, respectively.

[00204] Table 4. Mass ejection data for push mode devices before life testing

Type	Vibrating Member	Membrane	Ejector	Average Scale Ejection (mg)	Average Nicotine (µg)
II	H4	M11	R52	2.45	73.5
I	H5	M12	W11	3.30	99
I	H8	M15	W11	3.60	108

[00205] Table 5. Mass ejection data for push mode devices after life testing

Type	Vibrating Member	Membrane	Ejector	Average Scale Ejection (mg)	Average Nicotine (µg)
II	H4	M11	R52	3.26	97.8
I	H5	M12	W11	1.16	34.8
I	H8	M15	W11	1.54	46.2

[00206] Comparison of Push Mode and Prior Art Ring Mode

[00207] As set forth in Example 1 described subsequently, prototypes of BlueSky I and II push mode were tested and compared to prior technology, referred to as BlueSky ring mode (such as described and shown with respective test data for that technology in WO 2020/264501), is provided as follows:

[00208] Example 1

[00209] Ejectors with a hole size of 2.0 µm were tested in each device. Half of the ejectors tested had a hydrophilic entrance and hydrophobic exit (R). The other half had a hydrophobic entrance and exit (W). The testing was performed with a TSI Mini-MOUDI Model 135 and a Thermo Fisher Vanquish UHPLC. Eight different design combinations (vibrating members, membranes, ejector treatments) were tested with BlueSky I and II. Based on the results of the testing, push mode I appears to be the preferred embodiment for push mode. The push mode I design resulted in more consistent mass ejection and MMAD values versus II. Seven of the eight design combinations resulted in comparable mass ejections and MMADs. One outlier, H5 with M12 and R-treated ejector, had a significantly higher mass ejection than the others. Upon comparison of I push mode to BlueSky ring mode, I delivered higher and more consistent mass ejection and lower MMADs. Table 6, Table 7 and Table 8 provide the data obtained from ring mode, I push mode, and II push mode, respectively. The data in the tables include micrograms of nicotine ejected, MMAD, geometric standard deviation (GSD), and the percentage of ejected solution in stage 1 and stage 2 of the mini-MOUDI. All the vibrating member and membrane combinations tested with I push mode, found in Table 7, performed well with both ejector treatments. As seen in Table 8, the best performing combinations with II push mode were H4 with M11 and H5 with M12, both using W-treated ejectors.

[00210] Table 6**:** Ring Mode Mini-MOUDI results:

Treatment	Nicotine (µg)	MMAD (µm)	GSD	Stage 1 (%)	Stage 2 (%)	Stage 1 and 2 (%)
R	47.040	1.38	1.76	0.299	1.322	1.62
R	59.367	1.61	1.68	0.406	4.340	4.75
R	23.830	1.12	1.76	0.340	1.073	1.41
W	38.057	1.50	1.77	0.288	4.159	4.45
W	69.387	1.77	1.69	1.057	10.316	11.37
W	39.653	1.22	1.86	0.207	1.443	1.65

[00211] The results obtained from Push Mode I device are shown in Table 7. Tables 2 and 3 provide details of the referenced Vibrating Member and Membrane, respectively.

[00212] Table 7**:** Push Mode I Mini-MOUDI results:

Treatment	Vibrating member Style	Membrane Stye	Nicotine (µg)	MMAD (µm)	GSD	Stage 1 (%)	Stage 2 (%)	Stage 1 and 2 (%)
R	H4	M11	85.880	1.40	1.95	6.20	3.07	9.27
R	H4	M15	76.250	1.14	1.56	1.06	0.45	1.51
R	H5	M12	141.957	1.30	1.81	2.00	1.66	3.66
R	H8	M15	90.124	1.26	1.81	1.61	1.27	2.88
W	H4	M11	99.705	1.40	1.78	0.72	2.78	3.50
W	H4	M15	108.750	1.27	1.82	1.07	1.71	2.78
W	H5	M12	102.493	1.37	1.79	0.87	2.41	3.28
W	H8	M15	102.177	1.22	1.69	0.55	1.14	1.69

[00213] The results obtained from Push Mode II device are shown in Table 8. Tables 2 and 3 provide details of the referenced Vibrating Member and Membrane, respectively.

[00214] Table 8**:** Push Mode II Mini-MOUDI results:

Treatment	Vibrating member Style	Membrane Stye	Nicotine (µg)	MMAD (µm)	GSD	Stage 1 (%)	Stage 2 (%)	Stage 1 and 2 (%)
R	H3	M10	32.64	1.02	1.59	0.51	0.53	1.04

R	H4	M11	96.29	1.85	1.59	0.84	9.37	10.21
R	H5	M12	50.58	1.21	1.84	1.69	2.57	4.26
R	H7	M14	45.22	1.17	1.66	0.69	1.32	2.01
W	H3	M10	13.75	0.96	1.63	1.35	0.27	1.62
W	H4	M11	75.77	1.4	1.73	0.64	1.47	2.11
W	H5	M12	88.26	1.28	1.87	4.45	1.24	5.69
W	H7	M14	229.53	1.45	4.37	20.5	7.84	28.34

[00215] Based on the results of the testing, I push mode is the preferred embodiment when compared to II.

[00216] BlueSky Single Piece Cartridge and Low Cost of Goods Sold Designs

[00217] Another embodiment of push mode incorporates the two-part cartridge system into a singular component. Having the cartridge in one piece simplifies setup for the user and increases manufacturability while reducing cost. FIGS. 20, 21A and 21B show two single piece cartridge embodiments. The embodiment shown in FIG. 20 includes a long vibrating member with the fluid reservoir residing under the mesh. In this design, the container is two pieces that are assembled during manufacturing.

[00218] In another embodiment, there is a short vibrating member with the fluid reservoir above the mesh (see FIGS. 21A and 21B). In this design, the container is comprised of three pieces that are assembled during manufacturing. After the fluid reservoir is filled, the mouthpiece snaps onto the container with the container ring between.

[00219] The vibrating member and transducer work in conjunction with a membrane and mesh, as previously described embodiments of BlueSky push mode. The membrane also serves to isolate the vibrating member and transducer from the fluid. A mesh carrier is used in both designs. Magnets on the bottom of the containers hold the cartridge in the enclosure.

[00220] Further embodiments, shown in FIGS. 22A and 22B, of a single piece cartridge include a simpler design, reducing the COGS in manufacturing by decreasing the number of injection molded parts and bonds. FIG. 22A illustrates a simplified version of the design in FIG. 21A but with a long vibrating member. The design in FIG. 22A reduces the number of ultrasonic welds and injection molded parts. FIG. 22B further simplifies the design from FIG. 21A with fewer ultrasonic welds and injection molded parts.

[00221] The low COGS designs shown in FIGS. 23A and 23B are a simplification of the design shown in FIG. 21B. This design is a single part cartridge that can be inserted into the enclosure. Air exchanges between the seal of the mouthpiece and the upper container. The cartridges shown in FIGS. 22A-22B and FIG. 24 have removed the ejection port leaving the

10mm mouthpiece port. The preferable ejection port and mouthpiece port lengths are the same as previously set forth, 0mm-50mm.

[00222] BlueSky Two-Piece Cartridge

[00223] FIG. 24 illustrates a two-piece cartridge design for a long vibrating member. The container and ejector bracket are swapped where the ejector bracket is connected to the mouthpiece and the container is below. The spikes on the ejector bracket face downward onto the septa on the container.

[00224] Pharmacuetical/Therapeutic (Norway) Embodiments

[00225] Another embodiment of push mode, Norway, is similar to its BlueSky counterpart in most aspects, except that is tailored for prescriptive and medical use. Much like BlueSky, Norway features a releasable cartridge which contains a fluid reservoir and ejector bracket. The device can also be used to assess lung health using spirometry. FIG. 25 shows one embodiment of Norway push mode.

[00226] Patients diagnosed with lung diseases can use the Norway device to track their medication dosages and take lung function tests so their treatment progression can be assessed. The patient can perform lung function tests and view dosage history via a phone app which pairs to the Norway device with Bluetooth. The device saves pressure sensor measurements from each dosage of medication. Inspiratory flow measurements can be derived from the pressure sensor measurements to ensure the user is inhaling their medication at a flow rate which delivers the solution most efficiently. The device can also perform lung function tests to measure a patient's forced expiratory volume over 1 second, forced vital capacity, peak expiratory flow, and other spirometry measurements. The data from dosage tracking and lung function tests are uploaded to the cloud so that the patient and doctor may view the patient's progression.

[00227] The ejector bracket has been designed to accept many different sizes of containers, where the fluid reservoir volume changes. This makes the device capable of being used with biologics, or one time use ejections. Possible fluid reservoir volumes range from 1μL to 20mL.

[00228] The mouthpiece for the Norway embodiment has a preferred length of 15mm. There are two slits on the sides of the mouthpiece with a dimension of 9mm by 3mm for an area of 27mm^2. The length of the mouthpiece could be anywhere from 5mm to 30mm. The area for the mouthpiece could be from 1mm^2 to 100mm^2. The mouthpiece opening has dimensions of 14mm x 24mm for an area of 336mm^2. The area of the mouthpiece opening could be anywhere from 10mm^2 to 500mm^2.

[00229] The cartridge can be inserted into the main body of the device. The front of the cartridge can be sealed by an O-Ring attached to the cap that presses around the mesh on a stainless-steel annulus when closed to prevent any evaporation through the mesh, this is the face seal. The device features voice coaching and LED lights to guide the user through the ejection inhalation. There is an LCD screen to display dose count, and other necessary information. FIG. 26 shows an exploded view of one embodiment of Norway push mode.

[00230] Referring to FIGS. 27A-D, the cartridge assembly (FIG. 27A) is composed of three parts: the container (FIG. 27B), cartridge spacer (FIG. 27C), and the ejector bracket (FIG. 27D). The cartridge spacer keeps the ejector bracket separated from the container to prevent the fluid from contacting the mesh during storage prior to the push mode Initial use.

[00231] The cartridge spacer can be removed so the container can be pushed down onto the ejector bracket such that the spikes pierce the septa making the cartridge one piece. Then, the cartridge can be pushed into the main body of the device to complete the device. This process is illustrated in FIG. 28.

[00232] The cap of the Norway embodiment is designed to create a firm seal around the cartridge after each use. An O-Ring is seated on a spring-loaded plastic piece which lightly compresses onto the cartridge assembly when the cap is closed, generating a seal between the cartridge and open atmosphere. The components of the cap are shown isolated in as illustrated in FIG. 29.

[00233] The critical components to generate precise aerosol of the ejector bracket include the mesh, gasket, membrane, vent material, and mouthpiece. The membrane is positioned such that the membrane face is held parallel to the mesh face, or at a small precise angle. The ejector bracket also has two spikes protruding out of the top that pierce the container. One is for fluid supply, and the other provides a ventilation path for air generated by ejection. On the side of the ejector bracket with the air ventilation spike there is an opening covered by vent material to help relieve pressure and build-up of air. The mouthpiece is positioned following the face of the mesh.

[00234] The critical components of the container to maintain consistent aerosol are vent material, a spiral, septa, and septa caps. The vent material is positioned between the fluid and the spiral. The spiral is created by the upper container and vent spacer which minimizes evaporation of the fluid through the vent material. The vent spacer is bonded onto the top of the upper container to create the sealed spiral with an opening to the push mode Inside of the container assembly and another opening to atmosphere. The septa are at the bottom of the container. The septa are placed into a cavity in the lower container and held in place with septa caps that are bonded onto the lower container. The critical components of both the ejector bracket and container can be seen in FIGS. 30A and 30B.

[00235] The main body of the Norway contains the vibrating member and transducer assembly. In one embodiment, as shown in FIG. 31, the vibrating member and transducer assembly is encased by a vibrating member front cover and vibrating member rear cover. The covers are held together by circular caps called the front and rear vibrating member cover holders. The encased vibrating member is then put into the vibrating member enclosure, followed by the vibrating member assembly spring, and finally seated into the vibrating member device bracket. The vibrating member enclosure allows the spring to press the vibrating member and transducer assembly to the membrane.

[00236] Additional embodiments of Norway push mode include different suspension systems to hold the mesh in the cartridge, similar to those in BlueSky push mode. With the suspension systems seen in FIGS. 32 and 33, the vibrating member and transducer assembly no longer has a spring; therefore, it no longer needs to be in the vibrating member enclosure, nor does it need the vibrating member device bracket.

[00237] An additional embodiment of the Norway push mode device includes a heating element that increases the push mode Inhaled air temperature to roughly 50°C to make the dose more comfortable. As with the BlueSky designs that include heating elements, the heated air temperature is kept below thermal degradation levels, so the push mode Integrity of the formulation is maintained, and no harmful by-products are produced. This can be accomplished because, as with BlueSky, the device does not depend on heat to aerosolize. FIGS. 34A and 34B illustrate one design that includes two heating elements positioned beneath the vibrating member on either side of the ejector bracket. As seen in FIGS. 34A and 34B, air enters through openings in the bottom of the ejector bracket, passes through the heating elements, and exits into the mouthpiece. Additionally, the warmer air will cause minimal evaporation of the aerosolized fluid resulting in a decrease in MMAD.

[00238] Biocompatibility

[00239] In the push mode design, the vibrating member and transducer are completely isolated from the push mode Inhaled solution by a membrane. The transducer, which typically contains heavy metals, is located behind a vibrating member, such that it is completely removed from the ejection area and fluid reservoir. The membrane separates the fluid reservoir from the vibrating member, presenting a chemically inert barrier that permits little or no diffusion, and subsequent evaporation. In one embodiment, a palladium nickel alloy mesh is used to atomize the fluid. A polyimide mesh has also been tested and was shown to be a viable option. Using a polymer mesh would significantly reduce manufacturing cost and potentially improve the extractable/leachable profile of the device. The non-metallic components in prototyped embodiments are primarily comprised of cyclic olefin copolymer (COC) and silicone, both widely accepted materials used in the medical device industry.

[00240] Heated Air Design

[00241] FIGS. 35A-35C through FIG. 38 show embodiments which include a heating element to increase the push mode I inhaled air temperature to roughly 50°C, making the dose more comfortable. Air passes perpendicularly through the heating element to be most efficiently heated. Since the heated air temperature is kept below thermal degradation levels, the push mode Integrity of the formulation is maintained, and no harmful by-products are produced. Also, the specific heat of the fluid is much greater than air; therefore, the temperature of the aerosolized fluid will heat minimally. This can be accomplished because the device does not depend on heat to aerosolize. Here, the heat is only used to optimize the user experience. Additionally, the warmer air will cause minimal evaporation of the aerosolized fluid resulting in a decrease in MMAD. Finally, the heating element will be surrounded by insulation material to keep all the components of the device insulated from heat.

[00242] The heating element is breath actuated such that the element only heats air as the user inhales. This allows the battery to have a much longer life. It also creates a much safer device in that the heating element is not always on. This can be accomplished due to the push mode Incorporation of small gauge wire. This wire heats up very quickly, so the heating element responds as soon as the user inhales.

[00243] In the embodiment shown in FIGS. 35A-35C, after air enters the device, the air pathway is narrowed by the airflow accelerator to increase velocity. Then, the air is passed through the heating element, which is positioned in the heat exchange area. Finally, the heated air flows into the mouthpiece. FIGS. 35A-35C features three views of this embodiment. This design allows for a larger battery to be installed in the device which supplements the heating element.

[00244] Referring to FIG. 36, a speaker can also be incorporated into any of the heated air BlueSky embodiments. This will allow for an additional sensory experience for the user (i.e., crackling/heating sound upon inhalation).

[00245] In the embodiments shown in FIG. 37 and FIG. 38, the heating element is positioned below the vibrating member in a separate chamber inside the enclosure. The air enters through the airflow inlet, is passed through the heating element, and exits above the ejector. This design can be used in the two-part cartridge design (FIG. 37) or the single piece cartridge design (FIG. 98). These embodiments offer the advantage of a more compact device, compared to the embodiment shown in FIGS 35A-35C, at the cost of battery life.

[00246] Another embodiment features external heating elements seated on the outside of the enclosure (FIG. 39). Air passes through the heating elements, enters the mouthpiece above the mesh, and exits through the end of the mouthpiece. This design may in some embodiments provide a removable heating element.

[00247] In another embodiment of a heated air push mode device, closed loop control is used to regulate the power delivered to the heating element. The power is adjusted to keep the airstream temperature constant and at safe levels. Referring to FIG. 40, the airstream temperature is measured by a temperature sensor such as an RTD. The power delivered to the heating element changes as a result of the temperature sensor readings.

[00248] In another embodiment of the heated air push mode device, open loop control is used to regulate the power delivered to the heating element. The power is adjusted to keep the airstream temperature constant. The pressure drop from inhalation is sensed. The amount of power needed to supply the heating element to keep the air stream temperature constant due to changes in pressure drop is known. A look-up table is created to determine the amount of power needed to supply the heating element to keep the air stream temperature constant based upon the pressure sensor value.

[00249] In another embodiment of the heated air push mode device, one or more of the push mode Internal device components that are in contact with heated air is preferably made of metal (i.e., aluminum, Inconel, etc.). This will insulate the heating element and enhance biocompatibility of the device.

[00250] In another embodiment of the heated air push mode device, any component that could be compromised by the heated air is preferably made of metal (i.e., titanium, aluminum, Inconel, etc.). These components include, but are not limited to the mouthpiece, the heating chamber, and like components that heated air could negatively affect.

[00251] In one embodiment of the heated air push mode device, the metal components that are in contact with the heated air are preferably made of a material with a low thermal conductivity, such as Inconel.

[00252] In one embodiment of the heated air push mode device, ceramic is used to insulate the heating element.

[00253] Adjustable Air Resistance Design

[00254] Another embodiment of push mode incorporates a mechanism to adjust the size of the airflow inlets. The airflow inlets can be opened and closed using a sleeve or an adjustable aperture. In this way, the resistance experienced by the user can be adjusted to individual preferences. FIGS. 41A and 41B show a BlueSky device with a sliding sleeve 1732 around the enclosure. The sleeve can be adjusted to partially or completely cover the airflow inlets, increasing the resistance felt by the user. Additionally, the airflow in the mouthpiece will change as the position of the sleeve is changed. This will also change the MMAD of the dose due to changes in the airflow current.

[00255] Nasal Device Embodiments

[00256] BlueSky push mode has also been adapted for nasal inhalation. FIGS. 42-44 show several embodiments of a nasal BlueSky push mode device. As seen in FIGS. 42-44, there are multiple variations of the push mode Inhalation port. However, preferable embodiments of the nasal device have longer and narrower inhalation ports (see FIG. 42) than in other designs with shorter inhalation ports (see FIG. 43) for optimal nostril use. As seen in FIG. 44, a cap may be added to protect the push mode Inhalation port and keep it clean. The preferred droplet sizes are between 1–110 micron range, but 2-23 microns is preferred.

[00257] Additional Features

[00258] Hydrophilic/Hydrophobic tubes

[00259] Another embodiment of push mode incorporates a tube with a hydrophilic interior that supplies fluid from the fluid reservoir to the mesh. A hydrophilic tube eliminates the need for wicking material and allows for a wider variety of suspensions and solutions to be delivered from the device. An example of one of these tubes is the spike on BlueSky I and II.

[00260] Another embodiment of push mode incorporates a tube with a hydrophilic interior that supplies fluid from the fluid reservoir to the mesh without a wick material, allowing for a wider variety of suspensions and solutions to be delivered from the device; and an opposite hydrophobic tube that encourages gas migration from the fluid supply area between the membrane and mesh.

[00261] Polymer mesh holes

[00262] In another embodiment, as shown in FIG. 45, a polymer mesh 22 is used with a plate 45 attached to it. It has been found that a 2mm hole on a plate works best for ejection. Therefore, another embodiment is where the plate has multiple 2mm openings for the liquid to enter. The holes on the plate can range from 0.1mm-20mm.

[00263] Tidal Breathing

[00264] Another embodiment of push mode uses a tidal breathing system that can be used for pediatric therapy. The push mode technology supplies aerosol a mask similar to the Aero Chamber Plus Z-Stat Pediatric Mask (Monaghan Medical). This allows for long use therapy. When a user inhales, the device will start ejection and when the user exhales the device will stop ejection. Due to the robustness of push mode, this can be a very effective device for extended therapies.

[00265] Capacitance Cartridge

[00266] In another embodiment, two parallel plates 1528 surround the fluid next to the mesh and membrane area. These two parallel plates will measure the capacitance of the fluid. The capacitance of the supplied fluid is known. If the capacitance measured is different than the known capacitance, the device will not work. This will prevent tampering of the cartridge, and it will prevent unauthorized fluids to be inserted into the cartridge. One of the parallel plates is shown in FIG. 46.

[00267] Microfluidic Pump

[00268] Another embodiment of push mode utilizes vibrating member and membrane geometries at their coupled interface to act as both an atomizer and microfluidic pump in applications where wicking materials are not incorporated into the preferred embodiment for certain suspensions, solutions, and other medical, therapeutic, and consumer applications. The tip of the vibrating member is coupled to a membrane matching the desired geometry allowing fluid to enter between the mesh and membrane while also encouraging any gas to exit freely. These membranes may be treated by technologies mentioned previously to be hydrophilic or hydrophobic.

[00269] Another embodiment utilizes a separate microfluidic pump to direct the proper amount of fluid and pressure between the mesh and membrane when powered on, at breath actuation, at set intervals, etc. to ensure proper dosing.

[00270] Vibrating member geometry optimization

[00271] Vibrating members of the embodiments are to be made of materials featuring proper acoustical and mechanical properties. Thin film sputtering of various nonreactive metals such as titanium, palladium, gold, silver, etc. can be performed on the vibrating member tip section to further enhance biocompatibility. According to industry leaders, titanium has the best acoustical properties of the high strength alloys, has a high fatigue strength enabling it to withstand high cycle rates at high amplitudes, and has a higher hardness than aluminum, making it more robust. Correct material must be selected, vibrating members must be balanced, designed for the required amplitude, and be accurately tuned to a specific frequency. One aspect

of tuning is making the vibrating member have the correct elongated length. Another aspect of tuning is matching the vibrating member to the mesh and having the correct gain ratio. Incorrectly tuned vibrating members may cause damage to the power supply and won't be resonating at the device's optimized frequency, decreasing mass ejection and longevity. (*see also Ultrasonic Vibrating member catalog* - Emerson. Catalog - Ultrasonic Vibrating member (2014). Available at: https://www.emerson.com/documents/automation/catalog-ultrasonic-vibrating member-branson-en-us-160126.pdf. (Accessed: 2nd November 2021) – incorporated herein by reference.)

[00272] For example, Titanium 7-4 material has far more uniform wave propagation in one direction (axial) than Titanium 6-4.

[00273] Embodiments must have vibrating members with proper moduli of elasticity, acoustical properties, sound speeds, mechanical properties, molecular structure, etc. such as Ti Grade 23, Ti Grade 5, Ti Pure >99.9%, TIMETAL ® 7-4, 302 Stainless Steel, 303 Stainless Steel, 304 Stainless Steel, 304L Stainless Steel, 316 Stainless Steel, 347 Stainless Steel, Al 6061, Al 6063, Al 3003, etc.

[00274] Other embodiments have crystalline vibrating members with proper moduli of elasticity, acoustic properties, sound speeds, mechanical properties, molecular structure, etc. such as: Sapphire (Al2O3 Aluminum oxide), monocrystalline silicon, etc.

[00275] In one embodiment, vibrating member design is based on industrial ultrasonic vibrating member design such as disclosed by the push mode Indicated reference subsequently noted, but optimized to be used for the purposes of aerosol generation in the delivery of fluids to the lungs, nose, ear, eye, etc.

[00276] Referring to FIG. 47, the vibrating member is rectangular at the membrane interface. This rectangular tip features three periodic slots along the X directions and two periodic slots along the Y directions of the member tip based on a quasi-periodic phononic crystal structure.

[00277] Referring to FIGS. 48 and 49, the rectangular vibrating member tip combined with a conical section and a cylindrical section can effectively improve the output amplitude gain and utilizes the band gap property of the structure to effectively suppress lateral vibration of the vibrating member tip, improving the amplitude distribution uniformity at the membrane interface (*see also Lin, J. & Lin, S. Study on a large-scale three-dimensional ultrasonic plastic welding vibration system based on a quasi-periodic phononic crystal structure.* MDPI (2020). Available at: https://www.mdpi.com/2073-4352/10/1/21/htm. (Accessed: 2nd November 2021) – incorporated herein by reference).

[00278] In other embodiments, shown in FIGS. 50-58, the vibrating member 1708 is tuned and machined similarly to industrial ultrasonic vibrating member designs (such drawings being disclosed in the noted reference) but optimized for aerosol generation in the delivery of fluids to the lungs, nose, ear, eye, etc. such as contoured vibrating member (FIG. 50), plunger vibrating member (FIG. 51), product authenticity sensor vibrating member (FIG. 52), spool vibrating member (FIG. 53), slotted cylindrical vibrating member (FIGS. 54 and 55), bar vibrating member (FIGS. 56 and 57), and booster vibrating member (FIG. 58). *See also Industrial resonators* Available at: http://www.krell-engineering.com/fea/industr/industrial_resonators.htm. (Accessed: 2nd November 2021) – incorporated herein by reference.

[00279] Referring to FIG. 50, vibrating members can be contoured to make intimate contact with the membrane geometry.

[00280] Referring to FIG. 51, plunger members have nodally-mounted plungers that can be used to exert pressure on a given surface of the membrane contacted by the vibrating member.

[00281] Referring to FIG. 52, sensor carrier vibrating members feature an internal cavity partially or fully encapsulating a nodal-mounted sensing device. The sensing device is coupled with a sensor control unit which outputs a signal to the PCBA. This signal can be used to disable aerosol generation when non-compliant, incorrect, unlicensed, etc. cartridges are attempted to be used.

[00282] Referring to FIG. 53, spool vibrating members are unslotted cylindrical members featuring undercut sides behind the face to form a spool shape. This spool shape improves the face amplitude uniformity. Because a spool vibrating member does not have slots, its stresses are much lower than comparable slotted cylindrical vibrating members making machining costs much lower. Using cavities, slots, and back extension to optimize axial resonance creates a very uniform amplitude across the members face. The member is one half-wavelength long at axial resonance, as indicated by the single node that is generally transverse to the principal direction of vibration. Spool vibrating members generally have about 1:1 gain, although somewhat higher gain is possible.

[00283] Referring to FIGS. 54 (optimized) and 55 (unoptimized), slotted cylindrical vibrating members feature longitudinal slots used to reduce the transverse coupling due to the Poisson effect. Such slots are usually radial, although other configurations are sometimes useful. Without such slots, the vibrating member will either have very uneven amplitude across the face or may even resonate in a nonaxial manner. They also have a face cavity that extends deep within the member to increase its gain. The vibrating member is one half-wavelength long at axial resonance, as indicated by the single node that is generally transverse to the principal direction of vibration. Slotted cylindrical vibrating members generally have low-to-moderate gain (1:1 to 2:1).

[00284] Referring to FIGS. 56 (optimized) and 57 (unoptimized), bar vibrating members are rectangular and either unslotted or slotted only through the thickness. Special design techniques give optimum face amplitude uniformity. The vibrating member's thickness has been reduced in the blade section in order to provide reasonable gain. The vibrating member is one half-wavelength long at the axial resonance, as indicated by the single node that is generally transverse to the principal direction of vibration. Bar vibrating members generally have low-to-moderate gain (1:1 to 4:1).

[00285] Referring to FIG. 58, A booster is a coupling resonator that is placed between a transducer and vibrating member in order to change the member's amplitude and or as a means of supporting the resonator stack. The booster body is rigidly supported by a collar that is bonded to the booster's node. Because the rigid booster is constructed only of metal (no compliant elastomers), it has excellent axial and lateral stiffness. For additional stiffness a second collar can be incorporated into a full-wave design. The collar is tuned to isolate the motion of the booster body from the support structure. This is shown is the following image of a displaced booster, where the coolest colors indicate the lowest amplitudes. Each booster has a fixed gain (ratio of output amplitude to input amplitude), generally between 0.5:1 and 3.0:1.

[00286] With further reference to FIGS. 59-83, further alternative embodiments of vibrating members 1708 with vibrating member tip 170 that couple to transducers 26 of droplet delivery devices 10 in accordance with various embodiments of the disclosure are shown.

[00287] Other Vibrating Member and Membrane Alignments and Designs

[00288] In other embodiments, the vibrating member 1708 may include other shapes and the membrane 25 may also include alternative shapes. For example, FIG. 85A illustrates an ultrasonic transducer coupled to a rod-shaped vibrating member tip portion 170. FIG. 85 shows the vibrating member of FIG. 85A coupled to a centrally peaked or pointed membrane 25 in a droplet delivery device 10. FIGS. 85C and 85D show ultrasonic transducer 26 and membrane 25 of FIG. 85B in alterative embodiments wherein a mesh 22 includes first securing mechanism in FIG. 85C (see FIG. 2 and accompanying description) and second securing mechanism in FIG. 85D (see FIG. 3 and accompanying description).

[00289] FIG. 86A further illustrates in another embodiment an ultrasonic transducer 26 with a rod-shaped tip portion 170 coupled to a membrane 25 with a wide or dome/rounded exterior surface in a droplet delivery device 10. FIGS. 86B and 86C show ultrasonic transducer 26 and membrane 25 of FIG. 86A in alterative embodiments wherein a mesh 22 includes first securing mechanism in FIG. 86B (see FIG. 2 and accompanying description) and second securing mechanism in FIG. 86C (see FIG. 3 and accompanying description).

[00290] FIG. 87 shows an alternative embodiment of a droplet delivery service including an ultrasonic transducer 26 with rod-shaped vibrating member tip portion 170 offset from a central axis 220 of the droplet delivery device passing through the ejection channel 23, a slanted/sloped membrane 25 and mesh 22 and wherein the central axis of the vibrating member 230 is not aligned with central axis 220 of the device 10.

[00291] In another embodiment, FIGS. 88A and 88B illustrate an ultrasonic transducer 26 with a non-beveled ring-shaped vibrating member tip portion 170 coupled to a tilted mesh 22 in contact with a membrane 25 having a generally flat exterior top surface (nearest the mesh 22) in a droplet delivery device 10.

[00292] In further embodiment shown in FIG. 89A an ultrasonic transducer 26 with a beveled ring-shaped vibrating member tip portion 170 may be coupled to a slanted/sloped membrane 25 in contact with a membrane 25 in a droplet delivery device 10. FIG. 89B illustrates the slanted membrane 25 of FIG. 89A and FIG. 89E illustrate an ultrasonic transducer with a beveled ring-shaped vibrating member tip portion 170 also shown in FIG. 89A. FIGS. 89C and 89D show the ultrasonic transducer 26 and membrane 25 of FIG. 89A in droplet delivery devices in accordance with alterative embodiments of the disclosure wherein a mesh 22 includes first securing mechanism in FIG. 89C (see FIG. 2 and accompanying description) and second securing mechanism in FIG. 89D (see FIG. 3 and accompanying description).

[00293] FIGS. 90A and 90B show an ultrasound transducer 26 with a non-beveled ring-shaped vibrating member tip portion 170 coupled to a membrane with a generally flat exterior surface in contact and in a parallel plane to the plane of the fluid-entry underlying surface of mesh 22.

[00294] FIG. 91A and 91B show ultrasonic transducer 26 with a beveled ring-shaped vibrating member tip portion 170 coupled to a slanted/sloped membrane 25 with a space between the membrane 25 and the mesh 22.

[00295] FIGS. 90A and 92B illustrate an ultrasonic transducer 26 with a non-beveled ring-shaped vibrating member tip portion 170 coupled to a membrane 25 having a generally flat and parallel exterior surface relative to and not in contact with the underlying fluid-facing flat surface of the mesh 22 in a further embodiment.

[00296] FIGS. 93A-93D show an alternative embodiment of a droplet delivery device 10 with an ultrasonic transducer 26 having a wide and flat vibrating member tip portion 170 together with membrane 25 having a generally flat surface and mesh 22 being generally flat. A preferable suspension system for mesh 22 is further illustrated by FIGS. 30C and 30D.

[00297] FIGS. 94A-94D shown another embodiment with an ultrasonic transducer 26 having a wide and ring-shaped tip portion 170 together with membrane 25 having a generally flat surface and mesh 22 being generally flat. A preferable suspension system for mesh 22 is further illustrated by FIGS. 94C and 94D.

[00298] Membranes

[00299] The membranes 25 of the embodiments are made of materials featuring robust and proper acoustical and mechanical properties such as polyethylene naphthalate, polyethylenimine, poly ether ketone, polyamide, poly-methyl methacrylate, polyetherimide, polyvinylidene fluoride, ultra-high molecular weight polyethylene, and the like.

[00300] The membranes of the embodiments may have a hydrophobic coating, hydrophobic etching, hydrophilic etching, hydrophilic coating, roughening etch, etc.

[00301] In some embodiments, such as shown in FIGS. 96A-96D, membranes may include various shapes and surface textures, including “bumps” in one embodiment.

[00302] Meshes

[00303] Meshes 22 of the embodiments are to be made of materials featuring robust and proper acoustical and mechanical properties such as poly-methyl methacrylate, poly ether ketone, polyetherimide, polyvinylidene fluoride, ultra-high molecular weight polyethylene, polytetrafluoroethylene (PTFE), Ni, NiCo, Pd, Pt, NiPd, and metal alloys.

[00304] In one embodiment, the mesh is made from single crystalline or poly crystalline materials such as silicon, silicon carbide, aluminum nitride, boron nitride, silicon nitride, or aluminum oxide. Different hole shapes can be formed in a single crystalline wafer via high precision photolithography with and without using greyscale masks, and isotropic and/or anisotropic etches. Sputtered films can be deposited on the mesh to modify the wettability of the surface. Thin layers formed or deposited on the surface will have, in certain embodiments, much better adherence than films deposited on metal mesh formed by galvanic deposition or polymer mesh formed by laser ablation. The surfaces on the single crystalline wafers “slices” are atomically smooth and can be etched to produce exact surface roughnesses. Exact surface roughnesses can be used for better adherence of mechanical bonding with glue or other materials. Silicon carbide would be a preferable material because of its high strength and toughness. An important advantage of using semiconductor processes to fabricate hole

structures from a single crystalline wafer "slice" in a mesh of embodiment of the push mode invention is that the holes and surface contact angles will be exact without the variation seen in conventional ejector plates using mesh made from galvanic deposition or laser ablation. This mesh, as noted in Table 9 may be fixed as in II, or suspended as in I, and the membrane is coupled with an optimized vibrating member with a thin film sputtering of nonreactive metals such as palladium or gold member tip section to further enhance biocompatibility.

[00305] The hole structures of other embodiments are formed using semiconductor processes such as photo lithography and isotropic and anisotropic etching, laser ablation, femtosecond laser ablation, electron beam drilling, EDM (Electrical discharge machining) drilling, diamond slurry grinding, etc. See also FIGS. 109 and 110.

[00306] Table 9

Mesh Design	Embodiment	Brief Description
Single Crystalline Wafer	II	Fixed mesh coupled to optimized vibrating member
Single Crystalline Wafer	I	Suspended mesh coupled to optimized vibrating member

[00307] The meshes of the embodiments may have a hydrophobic coating, hydrophobic etching, hydrophilic etching, hydrophilic coating, roughening etch, etc. or a combination thereof.

[00308] In other embodiments, FIGS. 97-108 illustrate various implementations of polymer meshes utilized in push mode I and II devices.

[00309] Laminar Flow Element

[00310] In embodiments of the push mode invention, a laminar flow element 1600, such as shown in FIG. 1B, is preferably secured in the ejection port before the mouthpiece port of a droplet delivery device. In preferable embodiments, laminar flow element includes a plurality of cellular apertures. In some embodiments a laminar flow element includes blade-shaped walls defining the plurality of cellular apertures. In further embodiments, one or more of the plurality of cellular apertures include a triangular prismatic shape, quadrangular prismatic shape, pentagonal prismatic shape, hexagonal prismatic shape, heptagonal prismatic shape or octagonal prismatic shape. FIGS. 84A-84Q show various embodiments of a laminar flow element.

[00311] Preventing Oxygen Diffusion

[00312] Referring to FIG. 95, a droplet delivery device in an embodiment where an ejector bracket and container assembly are integrated as a single assembly includes a membrane cooperating with a mesh further preferably includes at least one superhydrophobic vent in such single assembly in fluid communication with the reservoir and is covered in storage with a removable aluminized polymer tab 3300 to help prevent oxygen diffusion into the fluid in the reservoir during such storage. In another embodiment of the push mode invention, a droplet delivery device in an embodiment where an ejector bracket and container assembly are integrated as single assembly that includes a membrane cooperating with a mesh further preferably further includes a removable aluminized polymer tab 3300 coupled to an exterior surface of the membrane adjacent the mesh during storage to help prevent oxygen diffusion into the fluid in the reservoir during such storage.

[00313] In another embodiment of the push mode invention, a droplet delivery device 10 having a membrane 25 that cooperates with a mesh 22 includes a pre-assembly step of removing a sealed packaging including aluminum and/or aluminum coating that contains the reservoir with a fluid, preferably wherein the reservoir is included in the container assembly that is also packaged for storage in the sealed packaging.

[00314] Decreasing Large Droplets in Aerosol

[00315] In embodiments of the push mode invention, it is desirable to decrease large droplet formation and encourage smaller droplet sizes to be delivered out of the droplet delivery device and in the aerosol stream.

[00316] In one embodiment, a hydrophilic wicking material may be provided to line the mouthpiece of the droplet delivery device. Droplets formed on the outer perimeter of a mesh exit are absorbed by the hydrophilic wicking material and decrease the likelihood of large droplets propelling off the surface of the mesh exit. This wicking material absorption of large droplets increases MMAD repeatability and prevents pooling.

[00317] In another embodiment, a one-dimensional hydrophilic lattice (see laminar flow element 1600 but taking such as a cross section), or a series of one dimensional hydrophilic lattices, may be used to absorb large droplets that might “pop” off the mesh due to pooling.

[00318] It has been noticed in tests of push mode droplet production that a fog of aerosol may remain within the mouthpiece tube after inhalation. This fog could lead to pulling on the mesh and along the outer perimeter. This pulling happens due to no entrained air pulling the tail end of the aerosol ejection out. Via electronic programming and monitoring through a microcontroller or microchip integrated or coupled in the droplet delivery device, the droplet device can be progammably controlled to start spraying when the air flow rate reaches a threshold and then the droplet delivery device detection controller records your maximum air intake every 2 ms. The droplet delivery device is programmed to stop spraying when the flow rate recedes to a percentage of the maximum flow rate achieved during inhalation. In embodiments, a parameter labeled "pressure cutoff" can be added to a graphical user interface (GUI) for control/programming of the droplet delivery device so that a manufacturer or other device operator and alter the stop condition parameter for the spray.

[00319] Referring to FIGS. 111A-111C, in another embodiment a baffle 4000 is inserted into the aerosol path. The baffle 4000 may comprise a plastic piece with fins 4050 to hold it in place in the aerosol tube of the droplet delivery device. The plastic piece has a cylindrical cavity which holds an absorbent plug 4100 (e.g., porous polyester or other wicking materials). The plug 4100 is inserted into the baffle cavity and is long enough to extend beyond the opening of the cavity. The absorbent plug faces the ejector mesh 22. On the side of the baffle opposite the mesh 22, the plastic baffle 4000 has a teardrop shape to direct airflow and prevent eddies from forming. The baffle 4000 is designed to inertially filter the aerosol by capturing large droplets in the absorbent plug 4100 upon ejection. Initial data using 3 ejectors is shown in the table below. As seen in Table 10, the baffle 4000 decreased the MMAD by approximately 0.1 – 0.2 um for each ejector. This inertial filtering creates a smoother inhalation experience with less irritation. The plastic piece of the baffle 4000 and the absorbent plug 4100 may be various lengths and/or diameters.

[00320] Table 10: Baffle Inertial Filtering

Sample	MMAD (um) without baffle	MMAD (um) with baffle
1	0.83	0.69
2	0.86	0.67
3	0.82	0.75

[00321] As described, it is important to get all the small droplets out of the mouthpiece. The small droplets have a very small stopping distance; therefore, the airflow must be close enough to the ejector plate to carry the small droplets. One design was tested wherein airflow directors were used to point the airflow towards the end of the mouthpiece and away from the mesh. As shown in FIG. 112, the airflow path with the airflow directors caused backwards eddies causing the small droplets to stay down by the ejector plate. Taking the airflow directors out helped the airflow catch some of the small droplets; however, the airflow was still leaving behind some of the small droplets. The holder for the ejector plate was sloped to help guide the airflow to the ejector plate. This encourages the air to catch most of the small droplets and send the droplets down the middle of the mouthpiece tube, but the ejector still produces larger unwanted droplets.

[00322] FIG. 113 illustrates the results when an insertable baffle 4000 was placed in the middle of the mouthpiece tube. This baffle holds a wicking material. As the airflow is pulled down the middle of the mouthpiece tube, the air flows around the baffle. The droplets follow the airflow; however, the larger droplets carry too much momentum and cannot make the turn to flow around the baffle. The larger droplets smash into the wicking material. The wicking material holds the liquid to keep the liquid from falling back onto the ejector plate. The liquid can then evaporate from the wicking material.

[00323] FIG. 114 illustrates additional results when an insertable baffle 4000 was also used with airflow directors. This test resulted in airflow coming from the airflow directors and shooting down the sides of the baffle. Eddies were still formed in the middle of the mouthpiece tube and pushed small droplets back onto the ejector plate. These eddies also caused the large droplets to flow around the baffle and resulted in no inertial filtering.

[00324] While the push mode invention has been described with reference to exemplary embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the push mode invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings without departing from the essential scope thereof. Therefore, it is intended that the push mode invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out this invention, but that the push mode invention will include all embodiments falling within the scope of the appended claims.

What is Claimed:

1. A droplet delivery device comprising:

a container assembly with a mouthpiece port;

a reservoir disposed within or in fluid communication with the container assembly and configured to supply a volume of fluid;

an ejector bracket in fluid communication with the reservoir, the ejector bracket including a mesh with a membrane operably coupled to a vibrating member that is coupled to an electronic transducer with the membrane between the vibrating member and the mesh, wherein the mesh includes a plurality of openings formed through the mesh's thickness and wherein the transducer is coupled to a power source and is operable to oscillate the vibrating member and the membrane and generate an ejected stream of droplets through the mesh; and

an ejection channel within the container assembly configured to direct the ejected stream of droplets from the mesh to the outlet.

2. The droplet delivery device of claim 1, wherein the electronic transducer is an ultrasonic transducer.

3. The droplet delivery device of claim 2, wherein ultrasonic transducer includes piezoelectric material.

4. The droplet delivery device of any of claim 1, wherein the container assembly is releasably detachable from the ejector bracket or releasably detachable together with the ejector bracket relative to one or more other detachable parts of the delivery device.

5. The droplet delivery device of claim 4, wherein the container assembly includes the reservoir.

6. The droplet delivery device of claim 5, further comprising the ejector bracket configured for releasably coupling to the container assembly and the ejector bracket further configured for releasably coupling to an enclosure system including the vibrating member, transducer and the power source.

7. The droplet delivery device of claim 6, further comprising magnets configured to releasably couple the ejector bracket and enclosure assembly.

8. The droplet delivery device of claim 1, wherein the reservoir includes a self-sealing mating mechanism configured to couple to a fluid release mating mechanism of the ejector bracket.

9. The droplet delivery device of claim 8, wherein the fluid release mating mechanism includes a fluid conduit configured for insertion into the self-sealing mating mechanism.

10. The droplet delivery device of claim 9, wherein the fluid conduit includes a spike-shaped structure with a hollow interior configured to provide fluid communication between the reservoir and the membrane.

11. The droplet delivery device of claim 1, wherein the membrane is configured not to contact the mesh.

12. The droplet delivery device of claim 1, wherein the membrane includes a slanted upper surface configured to contact fluid supplied from the reservoir.

13. The droplet delivery device of claim 12, wherein the vibrating member includes a slanted tip contacting an opposite underlying surface of the slanted upper surface of the membrane.

14. The droplet delivery device of claim 1, wherein the vibrating member includes a ring-shaped beveled tip.

15. The droplet delivery device of claim 1, wherein the vibrating member includes a ring-shaped non-beveled tip.

16. The droplet delivery device of claim 1, wherein the mesh has a top surface in a parallel configuration with a flat surface of a tip of the vibrating member

17. The droplet delivery device of claim 1, wherein the vibrating member includes a rod-shaped tip.

18. The droplet delivery device of claim 1, wherein the mesh has a bottom surface in a non-parallel configuration with an upper surface of the membrane.

19. The droplet delivery device of claim 18, wherein the mesh has a bottom surface slanted at an angle relative to the upper surface of the membrane.

20. The droplet delivery device of claim 1, further comprising a central axis of the droplet delivery device passing through the ejection channel and the membrane, and wherein the vibrating member includes a tip coupling to the membrane at a position offset from the central axis.

21. The droplet delivery device of claim 1, further comprising a fluid in the reservoir including at least one of non-therapeutic substance, nicotine, and cannabinoid.

22. The droplet delivery device of claim 1, further comprising a fluid in the reservoir including a therapeutic substance that treats or prevents a disease or injury condition.

23. The droplet delivery device of claim 1, further comprising a laminar flow element positioned in the ejection port of the container assembly before the mouthpiece port of the delivery device.

24. The droplet delivery device of claim 23, wherein the laminar flow element includes a plurality of cellular apertures.

25. The droplet delivery device of claim 24, wherein the laminar flow element includes blade-shaped walls defining the plurality of cellular apertures.

26. The droplet delivery device of claim 25, wherein one or more of the plurality of cellular apertures include a triangular prismatic shape, quadrangular prismatic shape, pentagonal prismatic shape, hexagonal prismatic shape, heptagonal prismatic shape or octagonal prismatic shape.

27. The droplet delivery device of claim 1, further comprising a breath-actuated sensor operatively coupled to the power source, wherein the breath-actuated senor is configured to activate the electronic transducer upon sensing a predetermined pressure change within the ejection channel or within a passageway of the droplet delivery device in fluid communication with the ejection channel.

28. The droplet device of claim 1, wherein the mesh comprises a material of at least one of palladium nickel, polytetrafluoroethylene, and polyimide.

29. The droplet delivery device of claim 1, wherein the mesh comprises a material of at least on of poly ether ketone, polyetherimide, polyvinylidene fluoride, ultra-high molecular weight polyethylene, Ni, NiCo, Pd, Pt, NiPd, and metal alloy.

30. The droplet delivery device of claim 1, wherein the membrane comprises a material of at least one of polyethylene naphthalate, polyethylenimine and poly ether ketone.

31. The droplet delivery device of claim 1, wherein the membrane comprises a material of at least one of metal membranes, metalized polymers, threaded polymers, threaded nylon, threaded polymers that are coated with polymers or metal, threaded nylon coated with polymers or metal, threaded metals, threaded SiC, threaded graphite composites, metalized graphite composites, graphite composites coated with polymers, polymer sheets filled with carbon fibers, poly ether ketone filled with carbon fibers, polymer sheets filled with SiC fibers, polymer sheets filled with ceramic or metal fibers, ULPA filter media, Nitto Denko Temic Grade filter media, Nitto Denko polymer sheets, threaded polymers bonded to a polymer sheet, nylon weave bonded to poly ether ketone or polyimide, graphite composites bonded to polymer sheets, polymer fiber weave with metalized coating, and nylon with sputtered on Al or vapor deposited Al.

32. The droplet delivery device of claim 1, wherein the electronic transducer is coupled to a vibrating member including a tip portion comprised of at least one of Grade 5 titanium alloy, Grade 23 titanium alloy, and about 99% or higher purity titanium.

33. The droplet delivery device of claim 1, wherein the electronic transducer is coupled to a vibrating member including a tip portion of a sputtered on outer layer of and about 99% or higher purity titanium providing a smooth tip surface configured to contact an underlying bottom surface of the membrane that is opposite an exterior top surface of the membrane positioned nearest the mesh.

34. The droplet delivery device of claim 1, wherein an exterior surface of the membrane, opposite an underlying surface of the membrane contacting the vibrating member, includes a hydrophobic coating.

35. The droplet delivery device of claim 1, wherein an exterior surface of the membrane, opposite an underlying surface of the membrane contacting the vibrating member, includes a hydrophilic coating.

36. The droplet delivery device of claim 1, wherein the mesh includes a hydrophobic coating on one or more surfaces of the mesh.

37. The droplet delivery device of claim 1, wherein the mesh includes a hydrophilic coating on one or more surfaces of the mesh.

38. The droplet delivery device of claim 1, wherein the mesh includes a hydrophobic coating on a first surface of the mesh and a hydrophilic coating on a second surface of the mesh.

39. The droplet delivery device of claim 1, wherein the membrane has an operable lifespan of over 55,000 aerosol-creating activations by the transducer.

40. The droplet delivery device of claim 1, further comprising at least one superhydrophobic vent in fluid communication with the reservoir that is covered with a removable aluminized polymer tab.

41. The droplet delivery device of claim 1, further comprising a removable aluminized polymer tab coupled to an exterior surface of the membrane adjacent the mesh.

42. A method for assembling a droplet delivery device of claim 1, comprising removing a sealed packaging including aluminum and/or aluminum coating that contains the reservoir with a fluid stored in the reservoir and coupling the container assembly to an enclosure system including the power source.

43. The method of claim 42, wherein the reservoir is disposed within the container assembly.

44. The droplet delivery device of claim 1, further comprising a snap mechanism and/or magnets configured to releasably couple the ejector bracket and the container assembly.

45. A droplet delivery device comprising:

a membrane supported in the device and coupled via a vibrating member to an electronic transducer; and

a mesh supported in the device between the membrane and a port in a mouthpiece or nostril insertion element, wherein the membrane, mesh and port are all in fluid communication with one another.

46. A method of producing a droplet stream from a fluid comprising delivering a fluid volume between a membrane and mesh, electronically activating an ultrasonic transducer

coupled to the membrane via a vibrating member and producing a droplet stream by pushing the fluid volume through openings in the mesh.

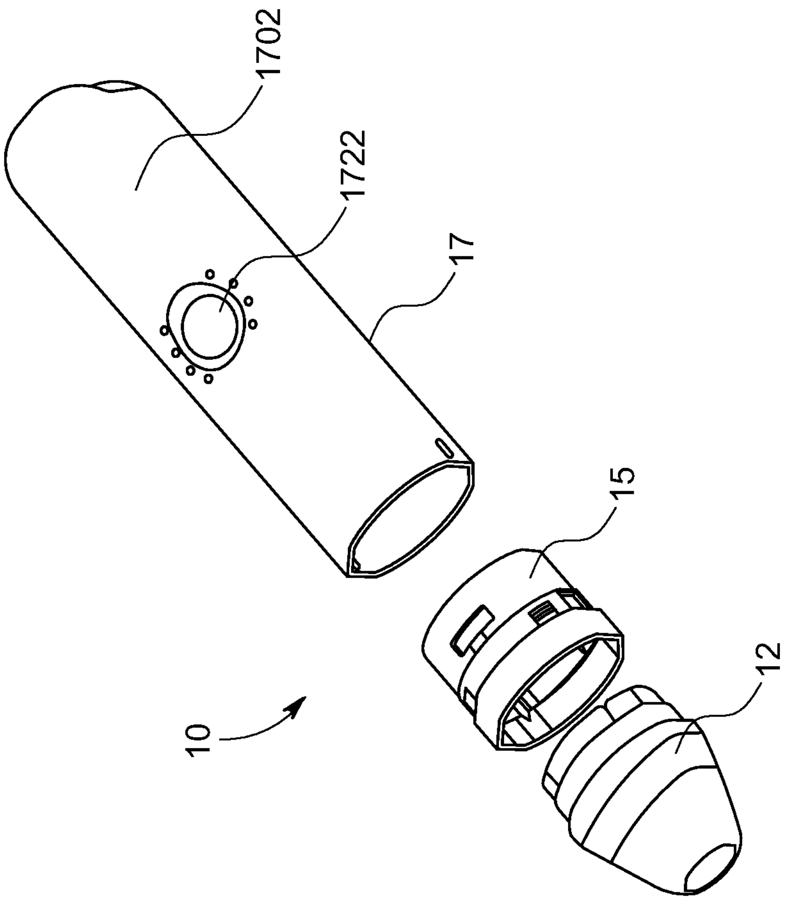


FIG. 1A

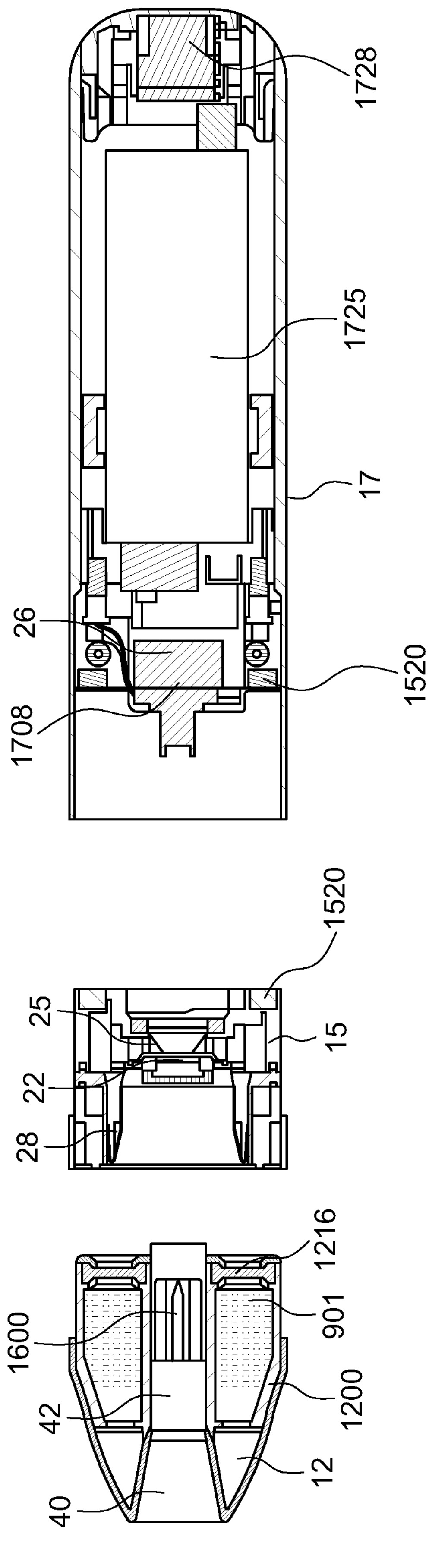

1728
1725
17
26
1520
1708
1520
25
15
22
28
1216
901
1600
1200
42
12
40

FIG. 1B

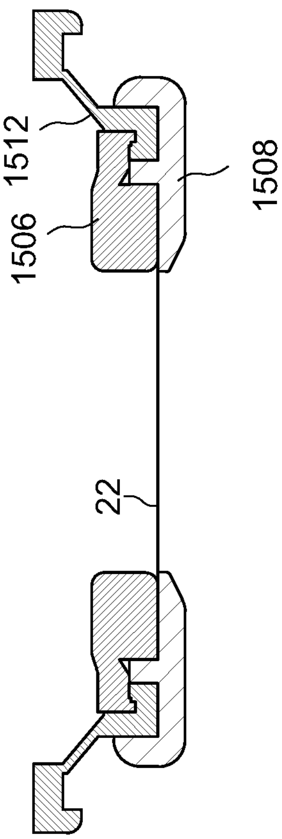


FIG. 3

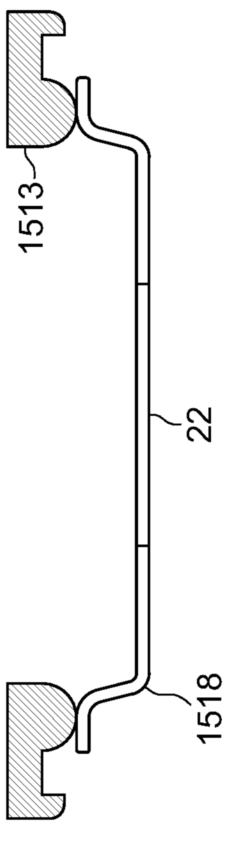


FIG. 2

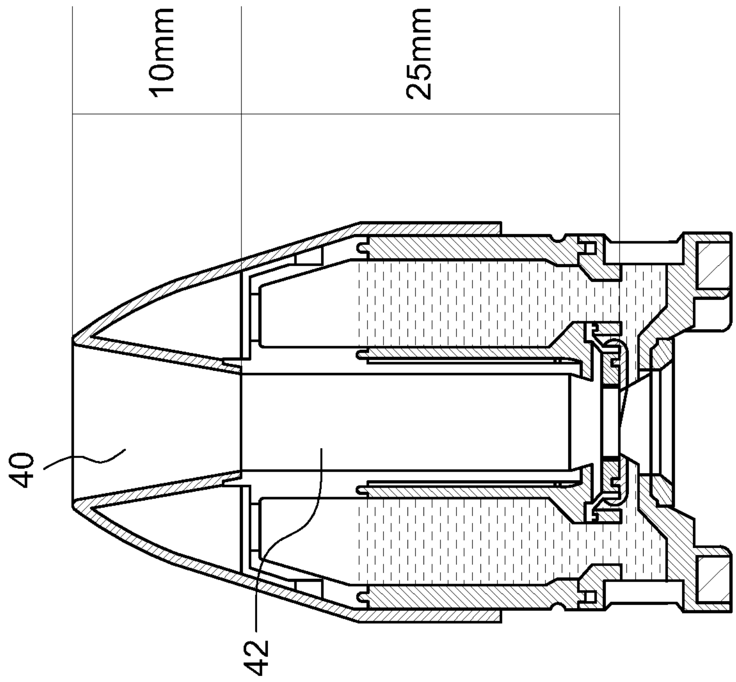
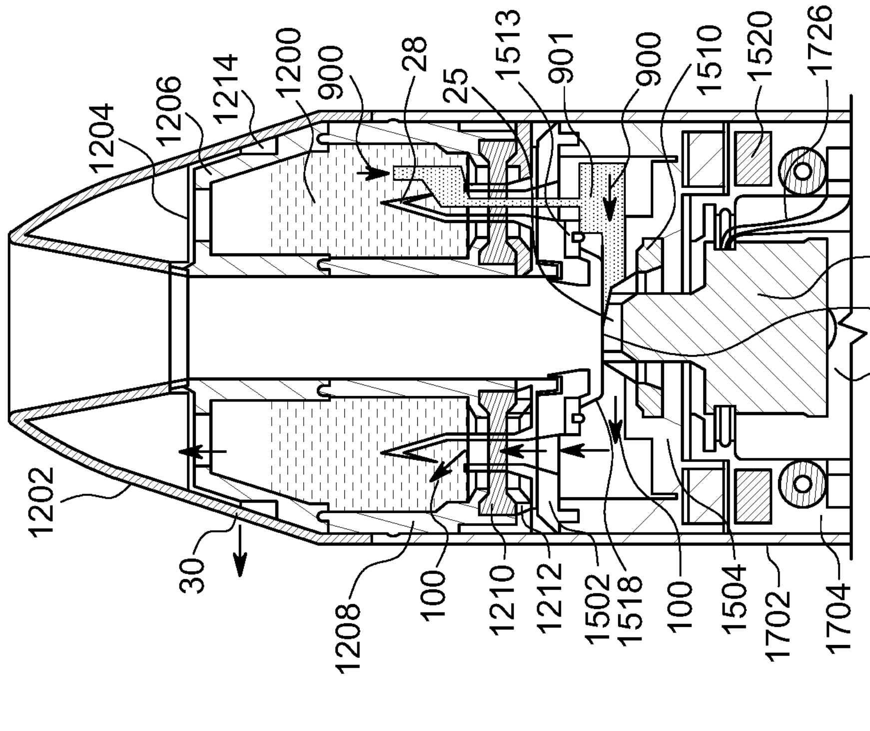


FIG. 4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1206
1214
1200
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28
25
1513
901
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FIG. 5

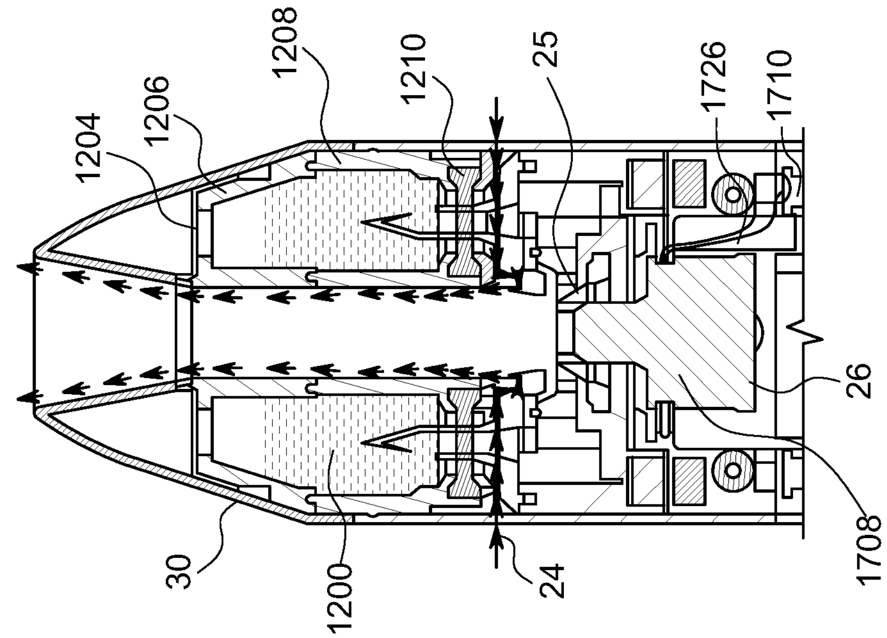

FIG. 6B

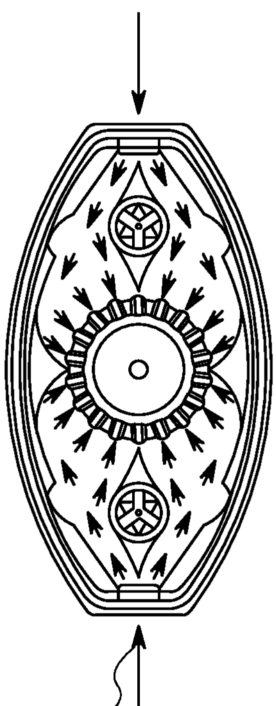

FIG. 6A

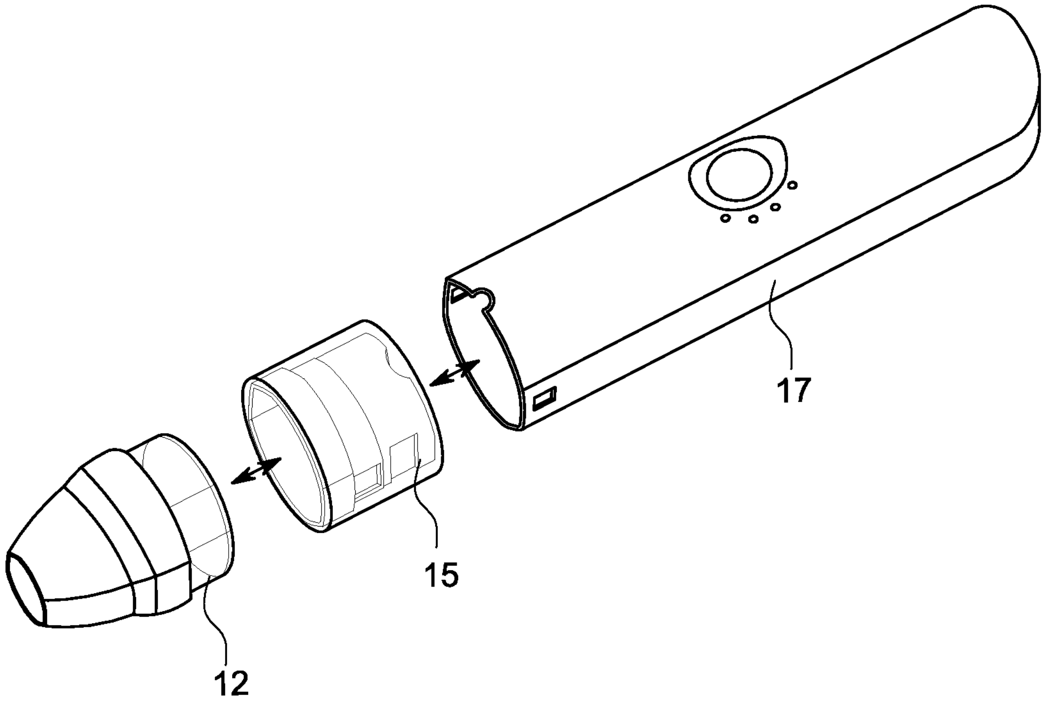

FIG. 7A

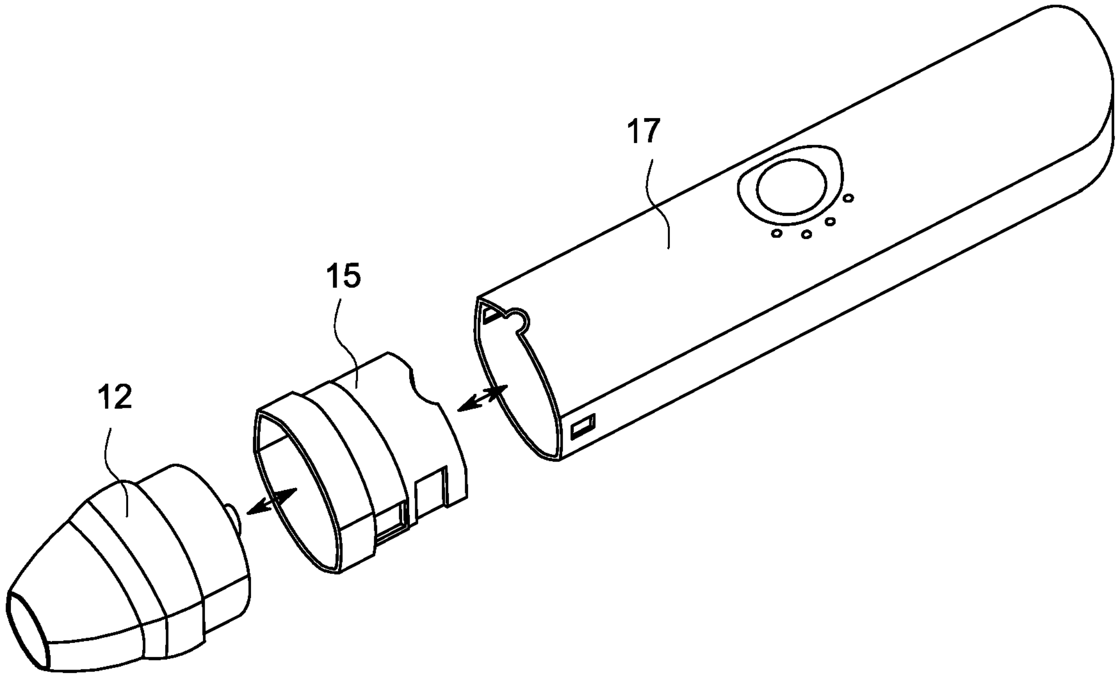

FIG. 7B

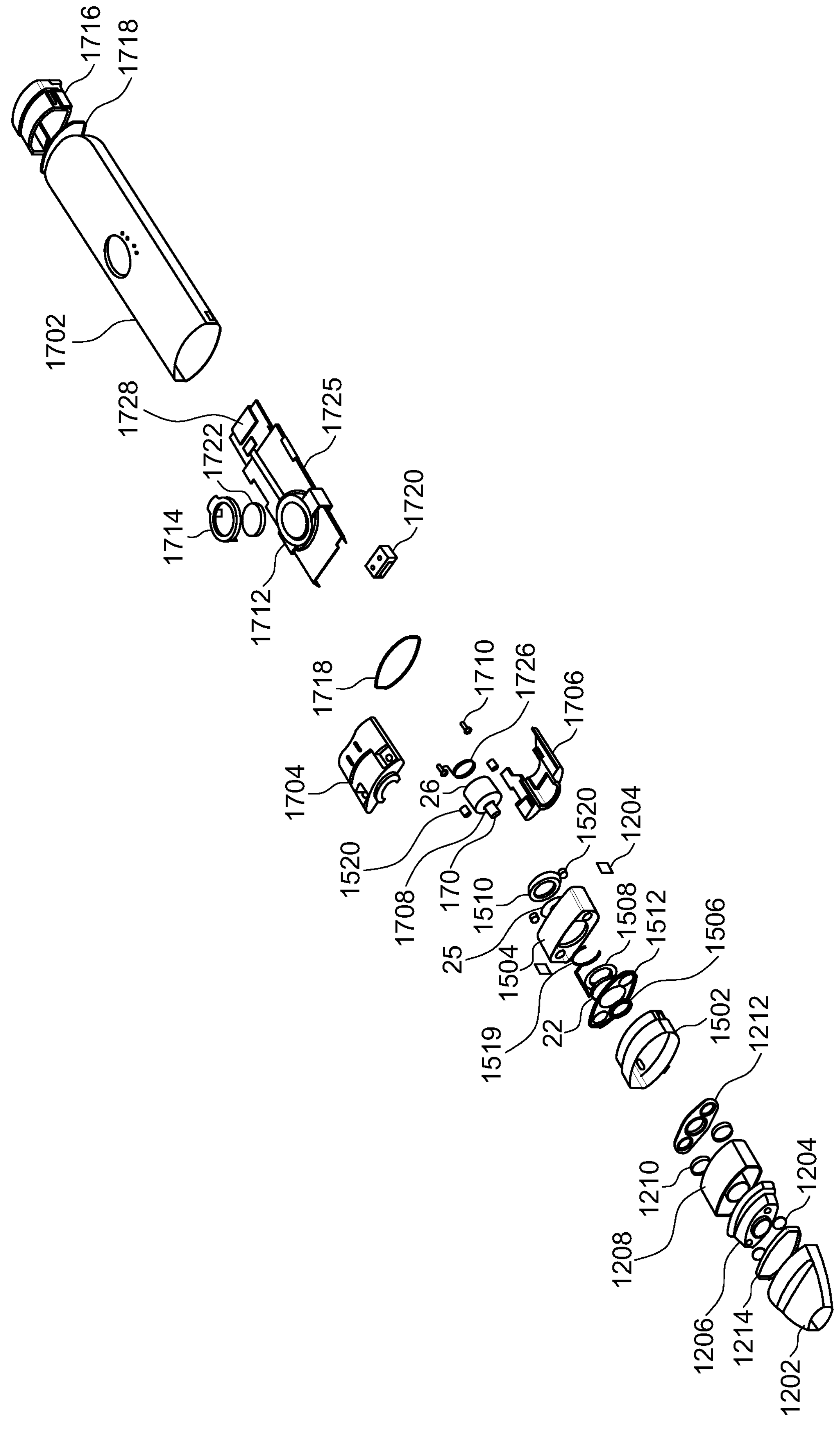
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FIG. 8

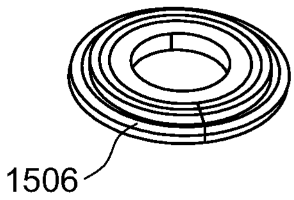

FIG. 9A

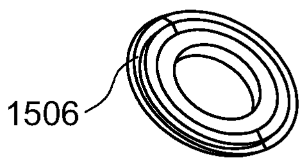

FIG. 9B

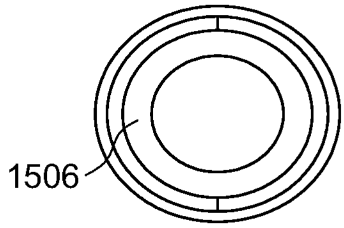

FIG. 9C

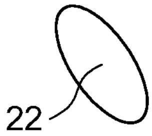

FIG. 9F

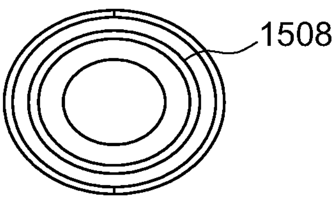

FIG. 9D

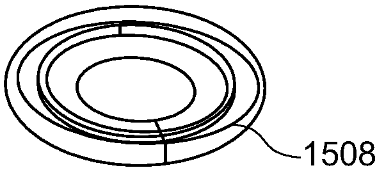

FIG. 9E

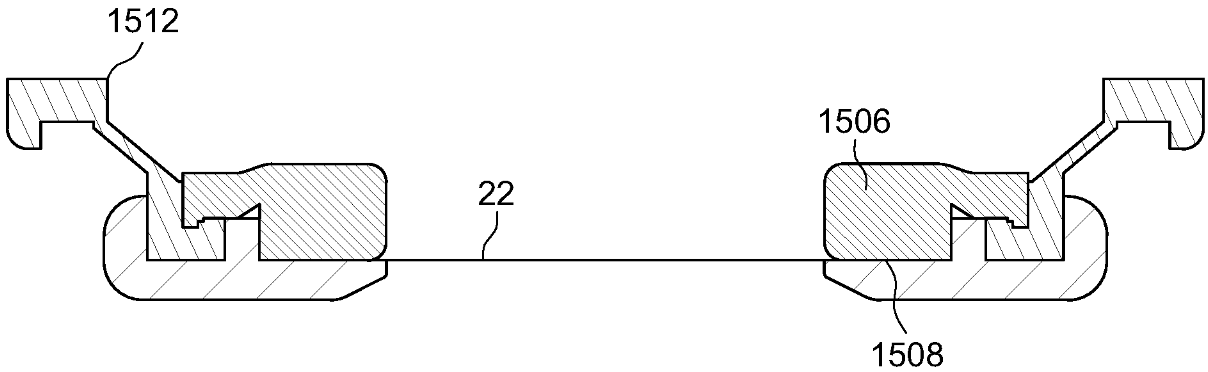

FIG. 10

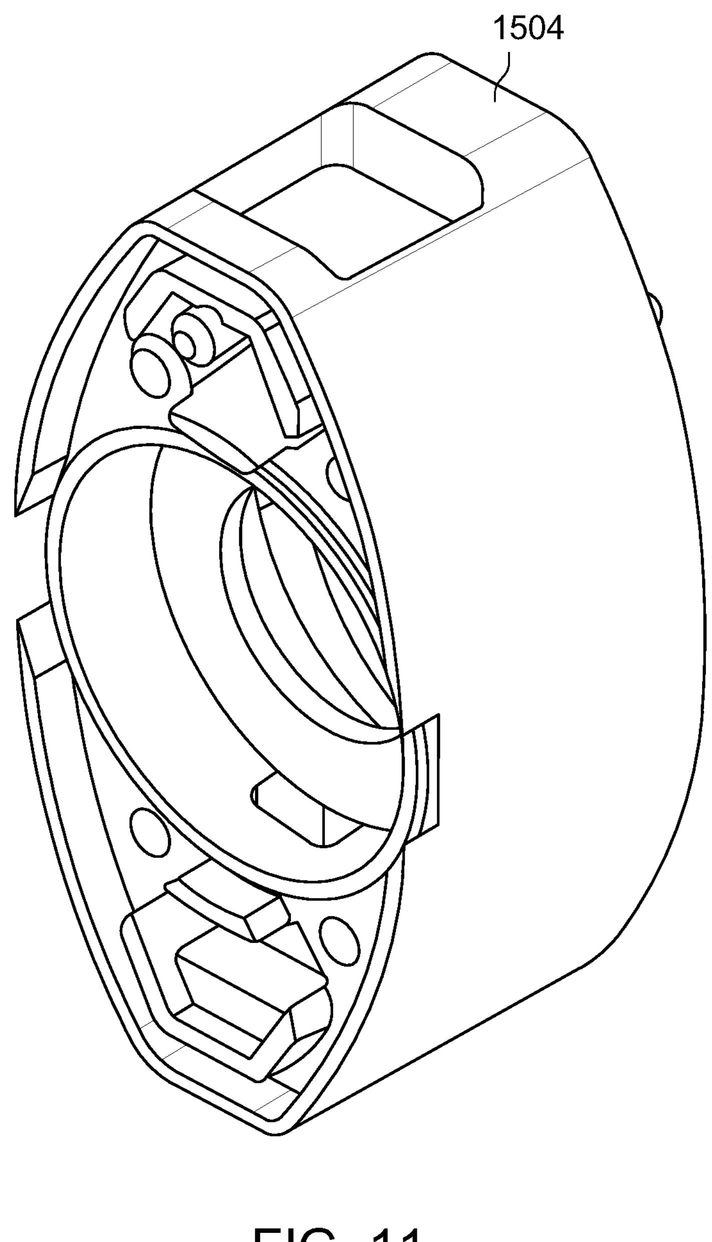

FIG. 11

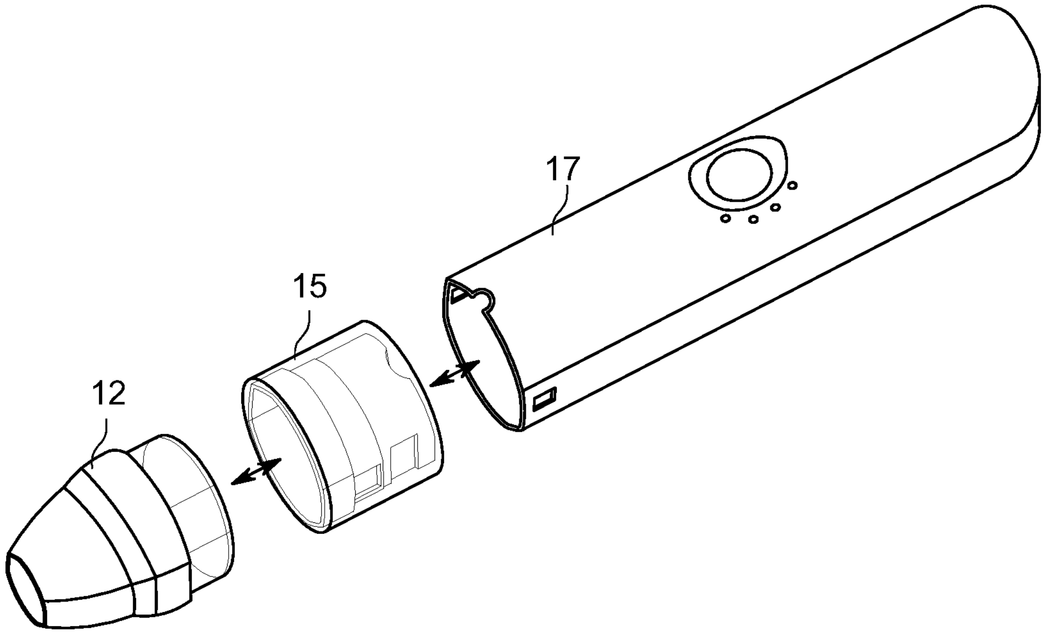

FIG. 12A

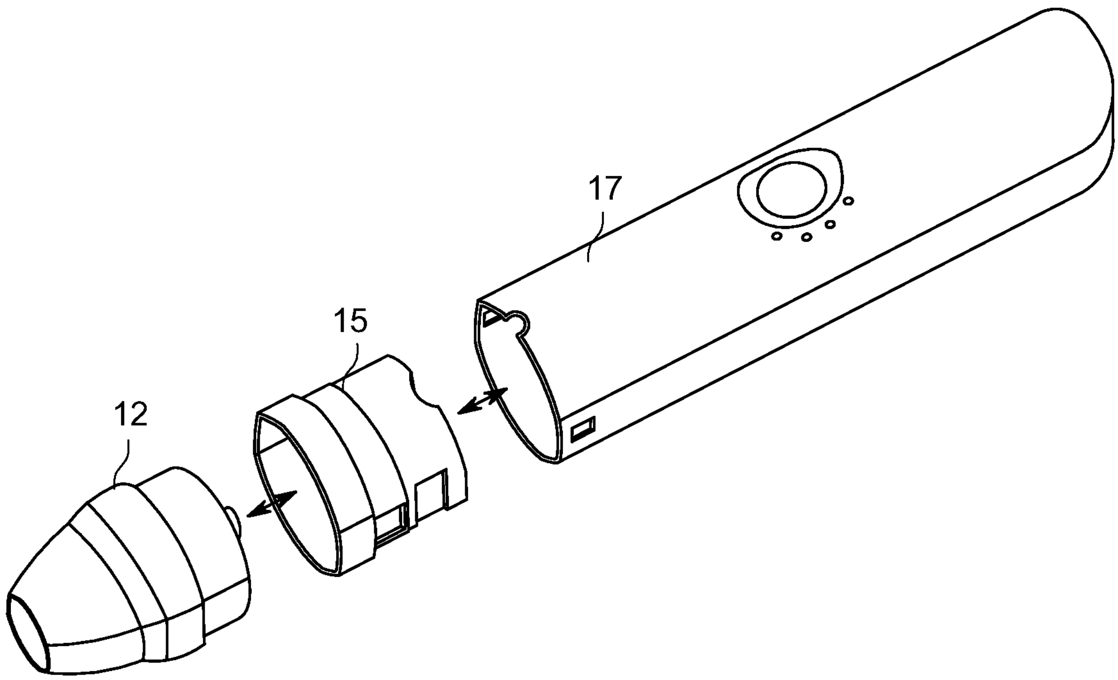

FIG. 12B

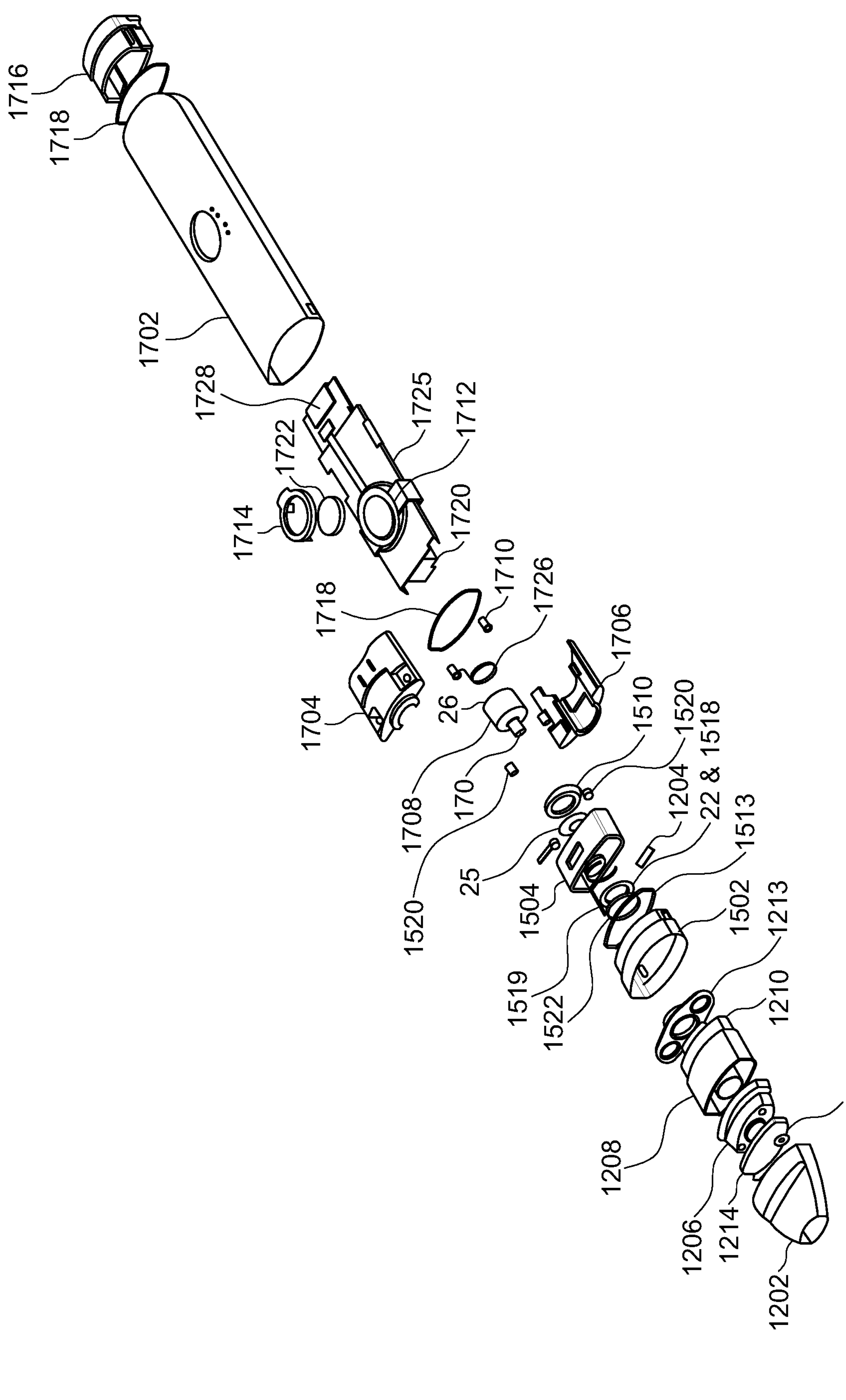
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FIG. 13

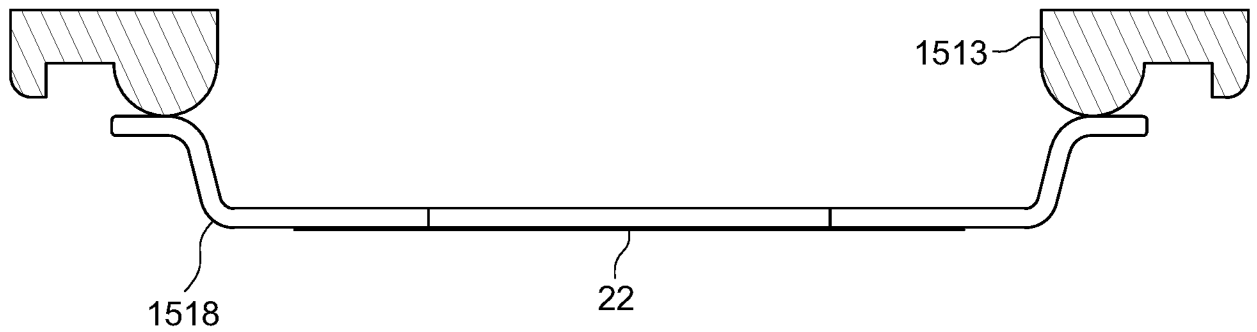

FIG. 14

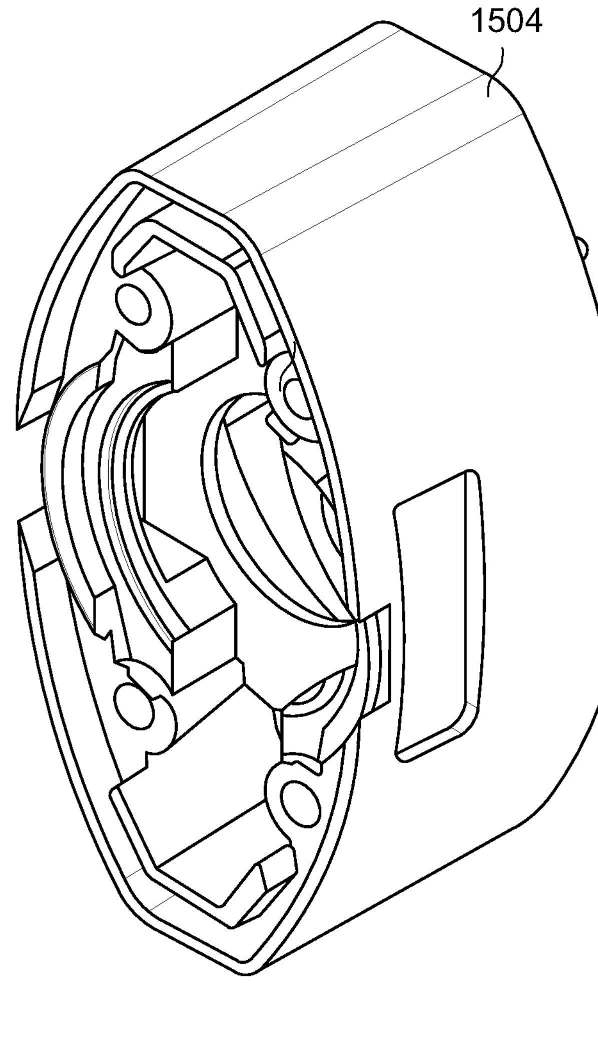

FIG. 15

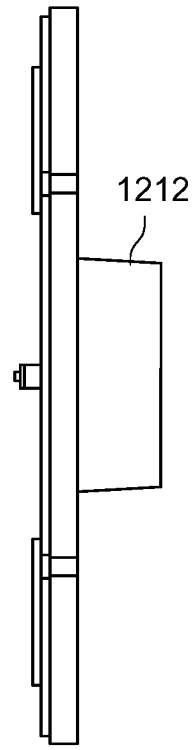

FIG. 16

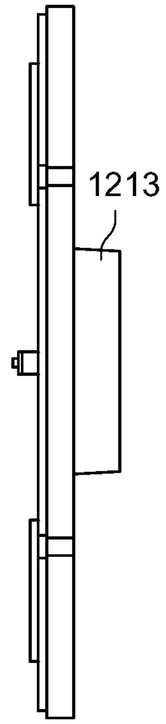

FIG. 17

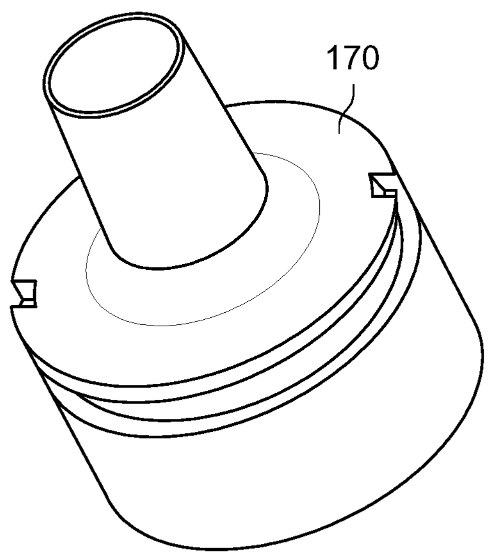

FIG. 18

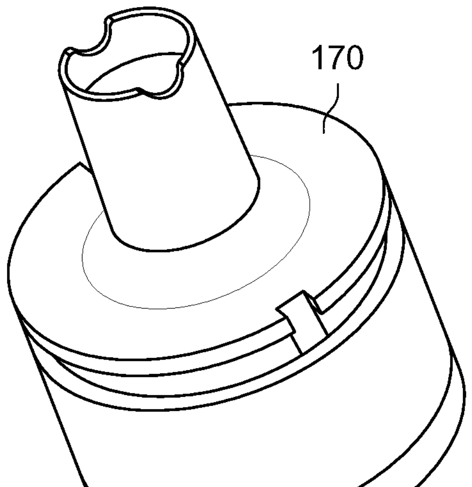

FIG. 19

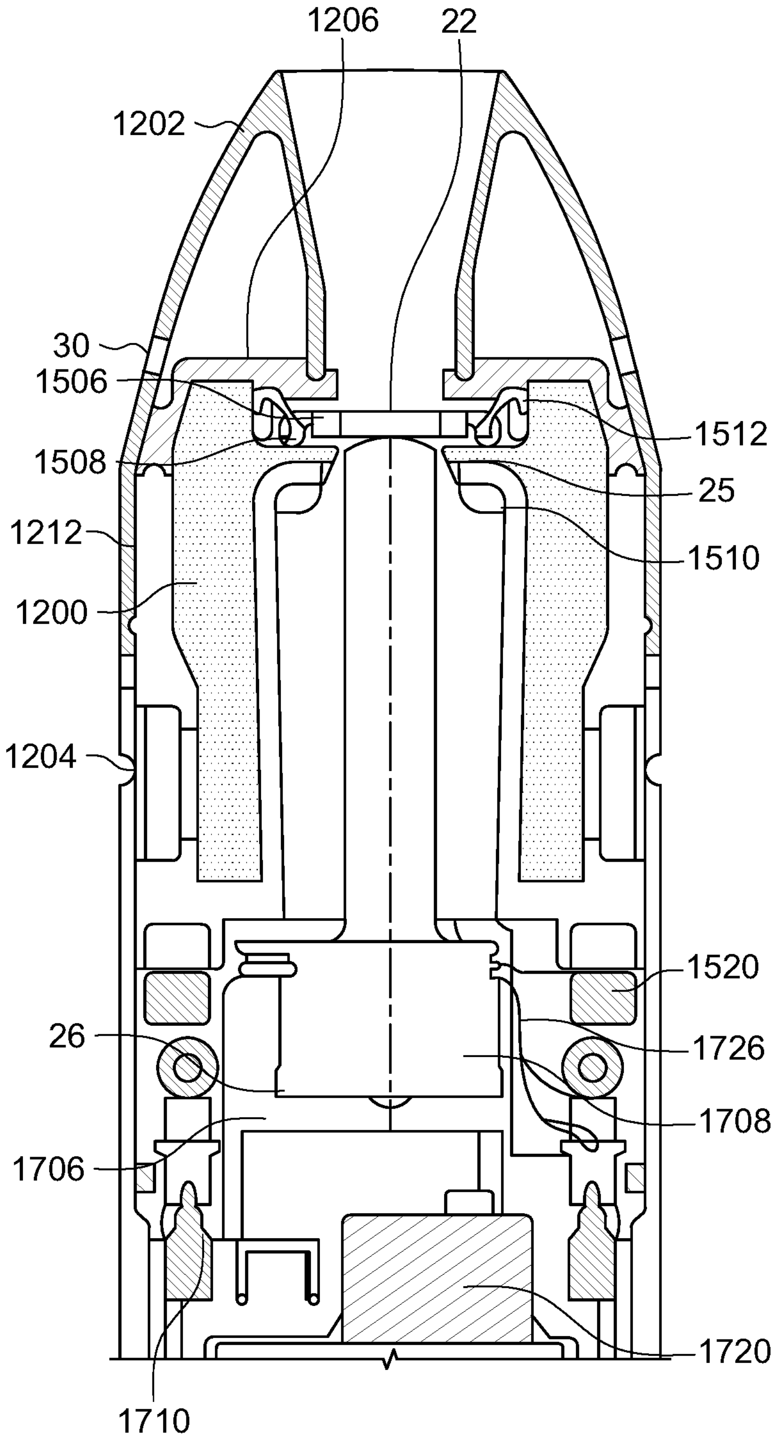
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FIG. 20

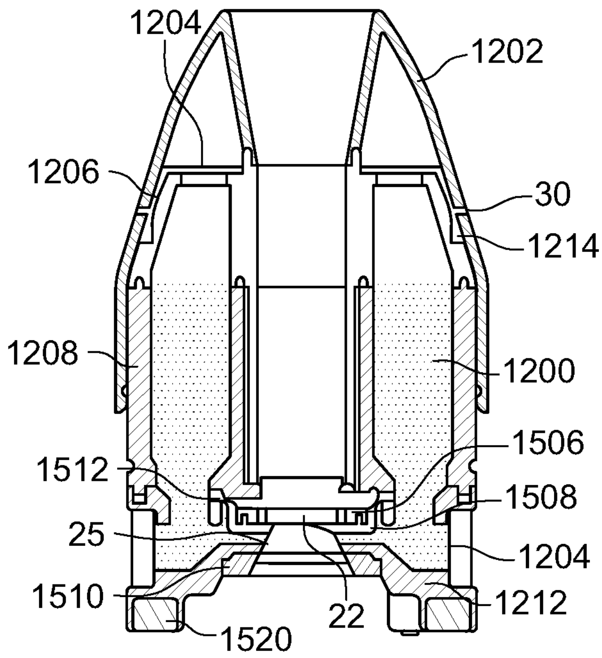

FIG. 21A

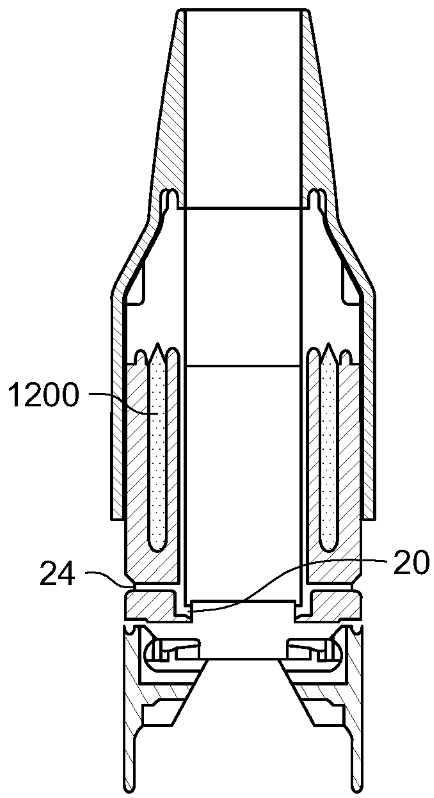

FIG. 21B

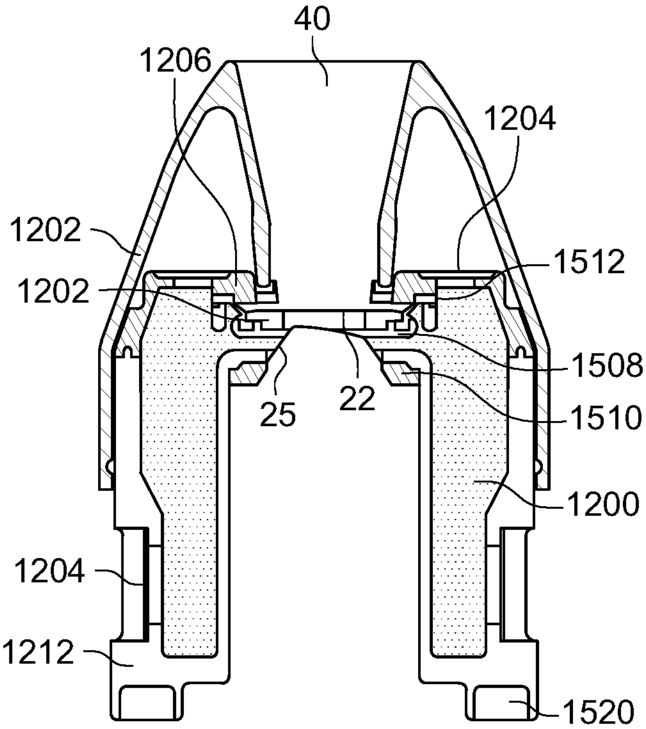

FIG. 22A

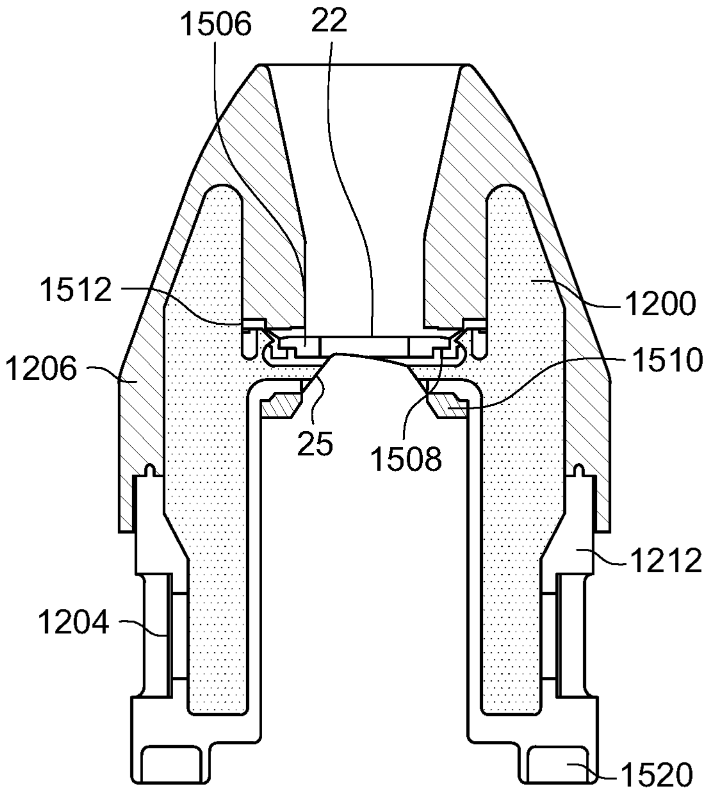

FIG. 22B

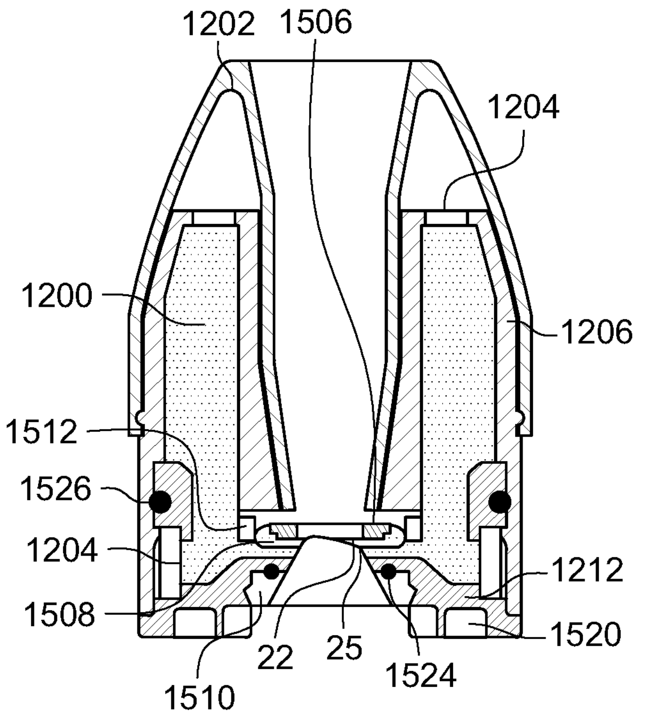

FIG. 23A

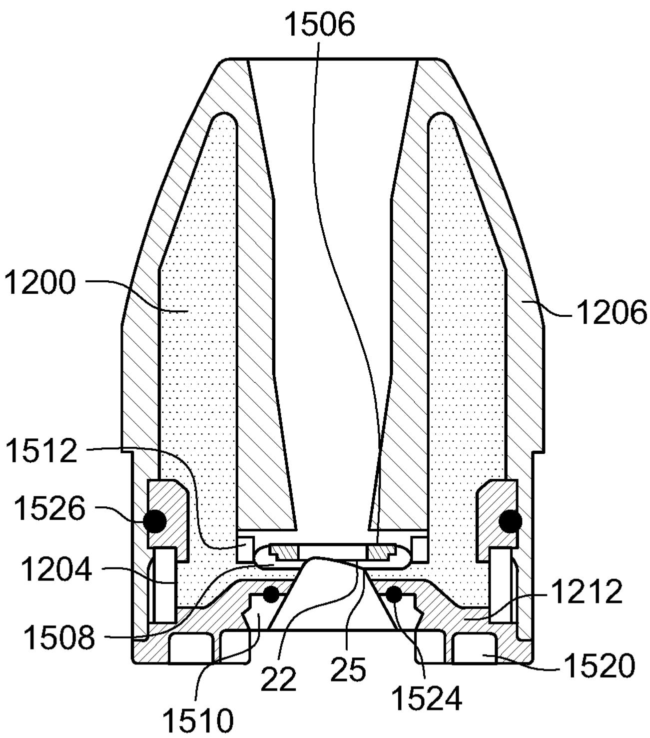

FIG. 23B

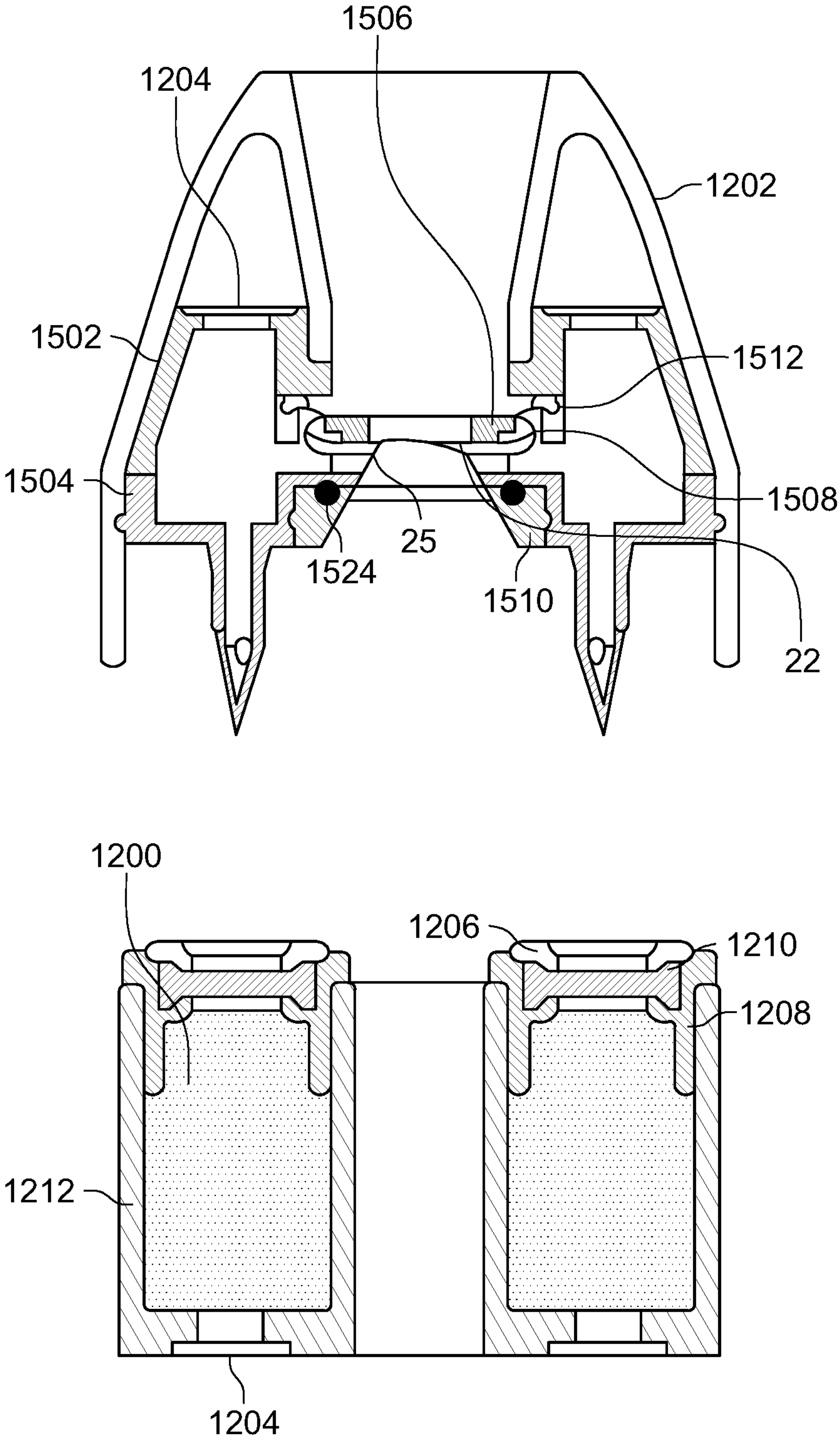
1506
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FIG. 24

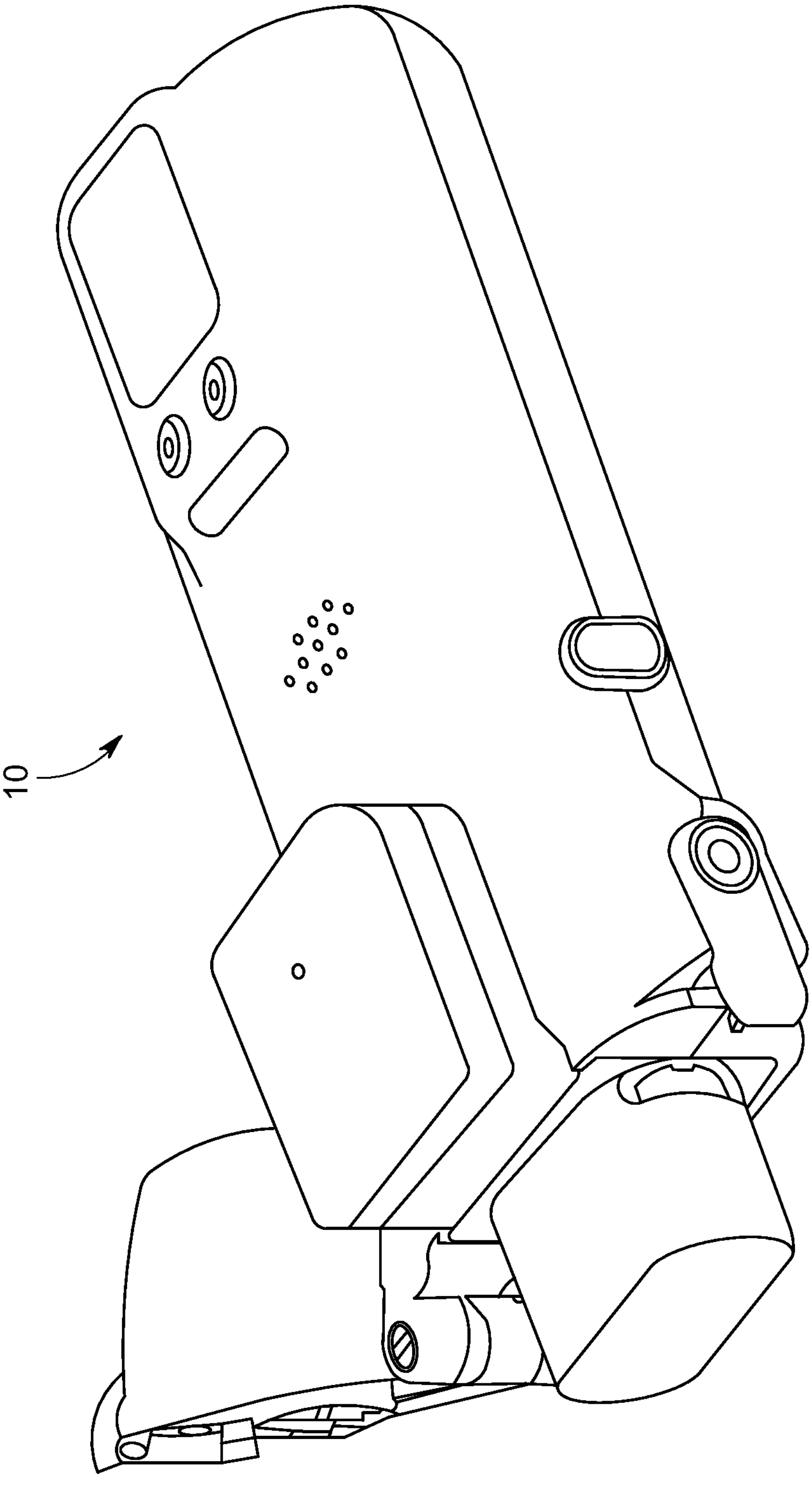

FIG. 25

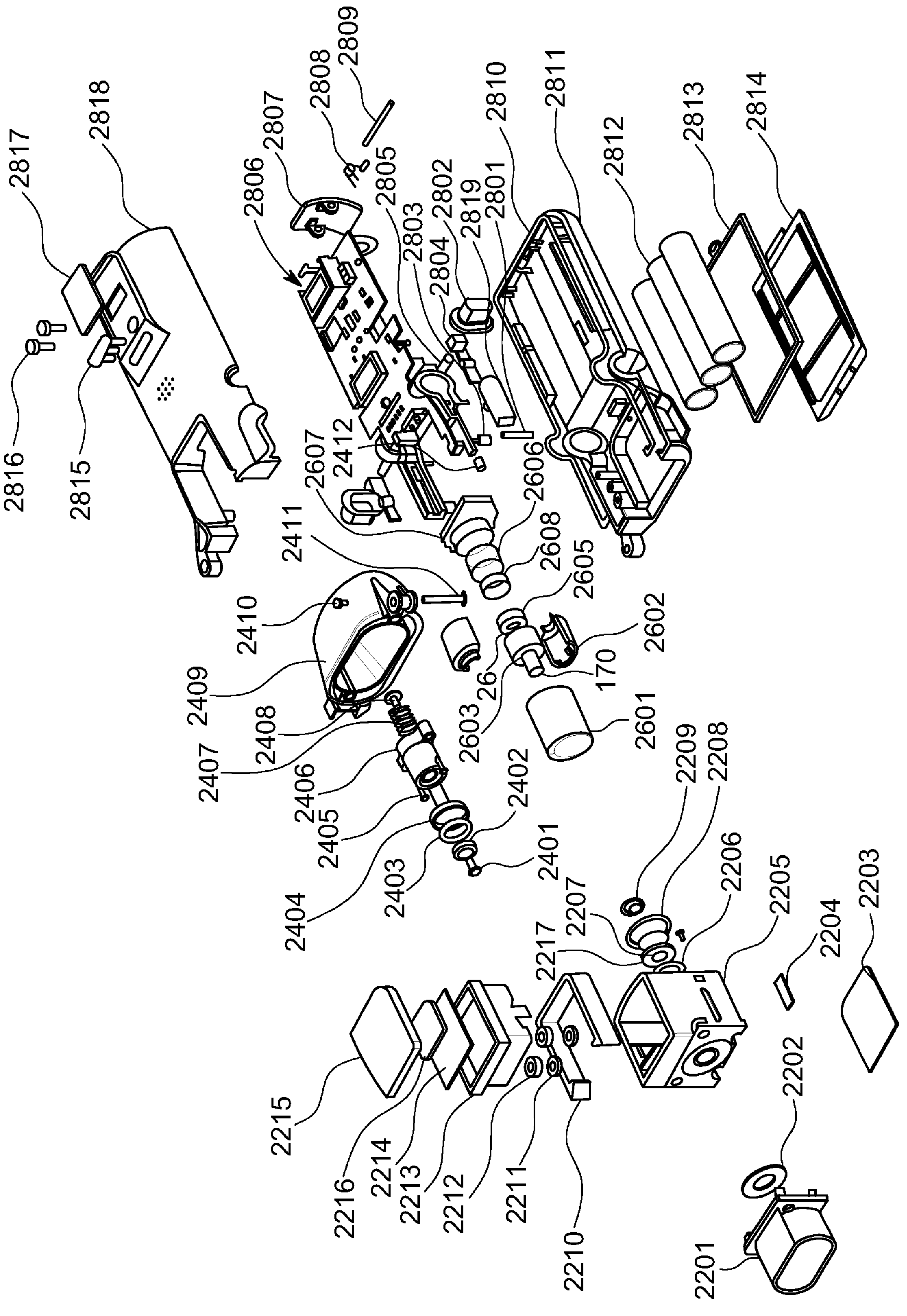
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FIG. 26

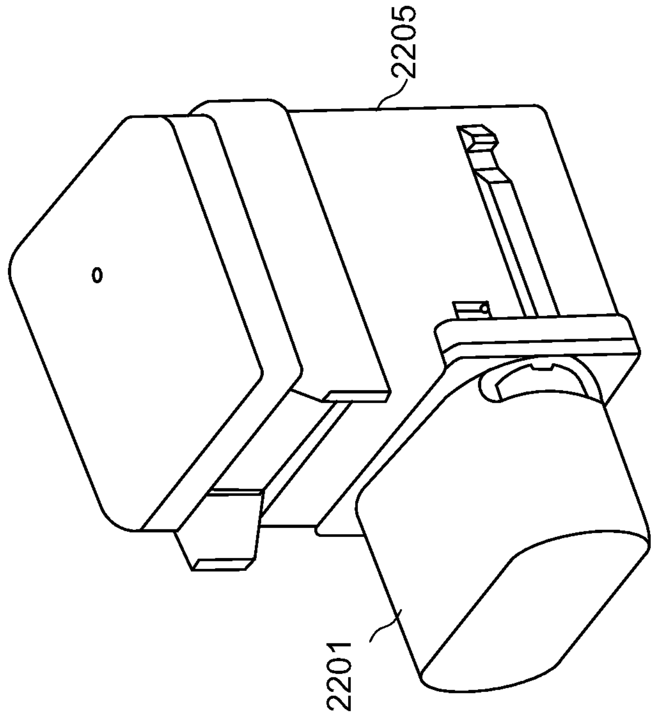

FIG. 27A

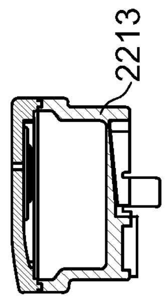

FIG. 27B

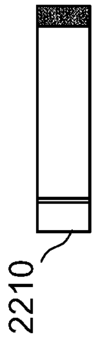

FIG. 27C

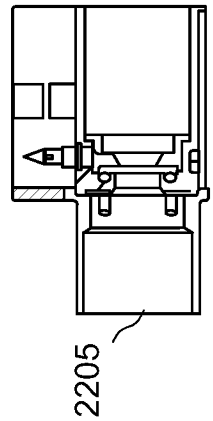

FIG. 27D

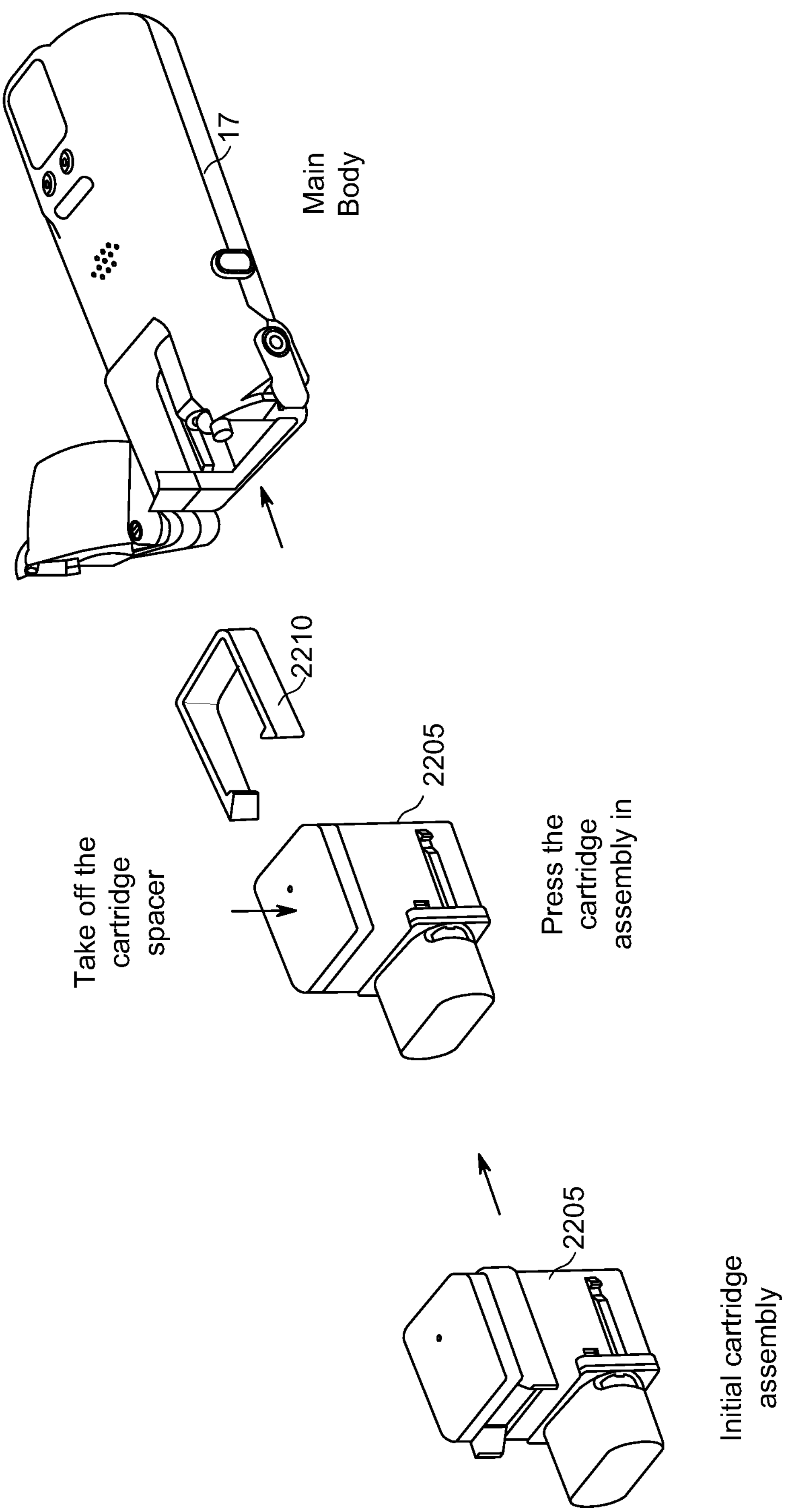
17
Main Body
2210
2205
Take off the cartridge spacer
Press the cartridge assembly in
2205
Initial cartridge assembly

FIG. 28

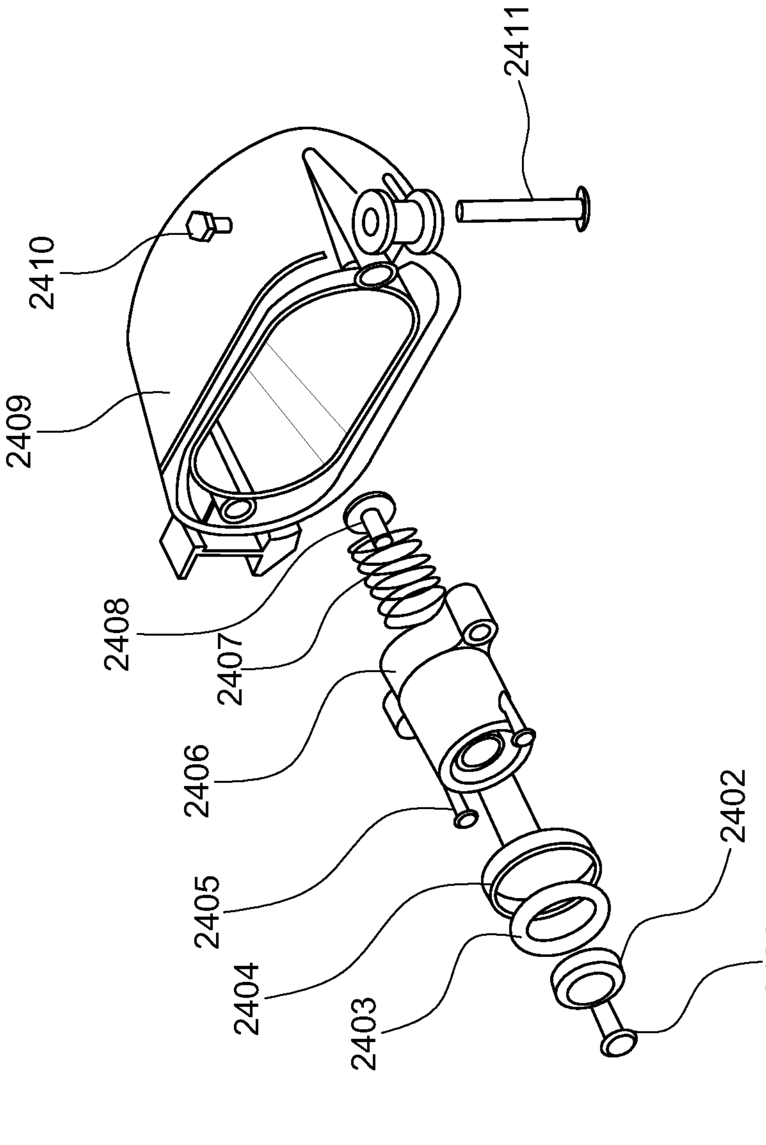

FIG. 29

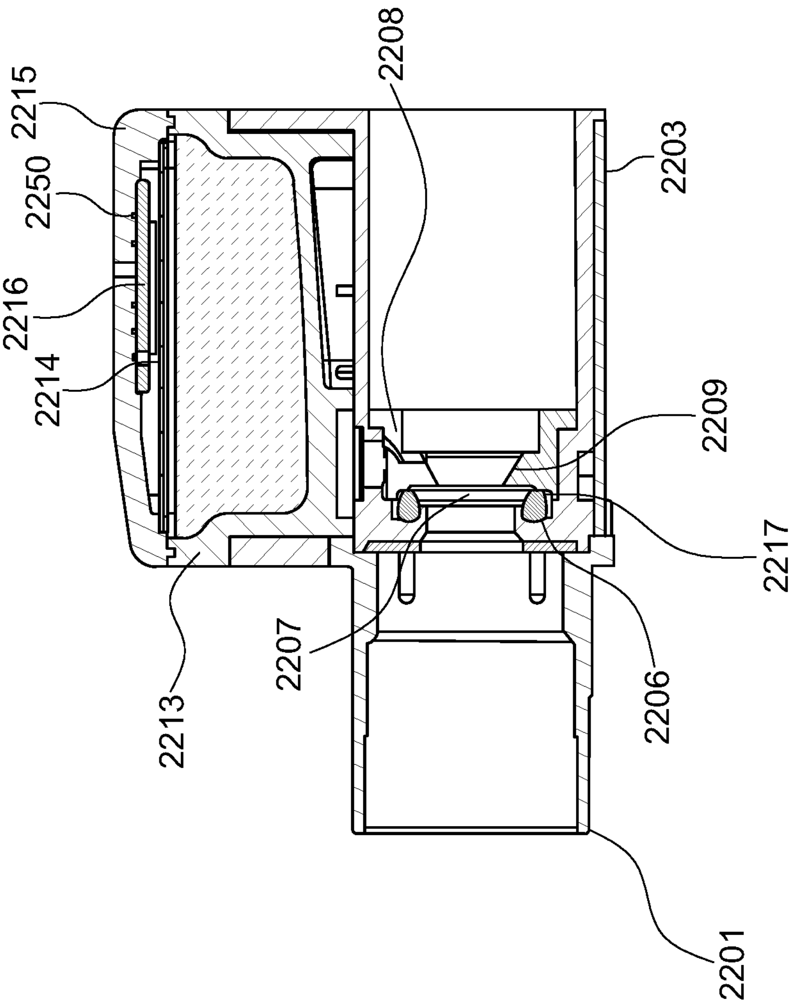

FIG. 30B

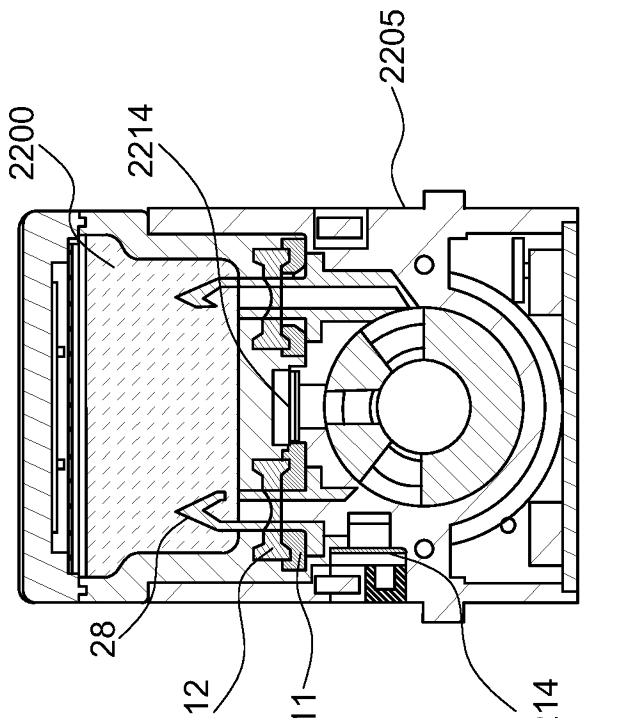

FIG. 30A

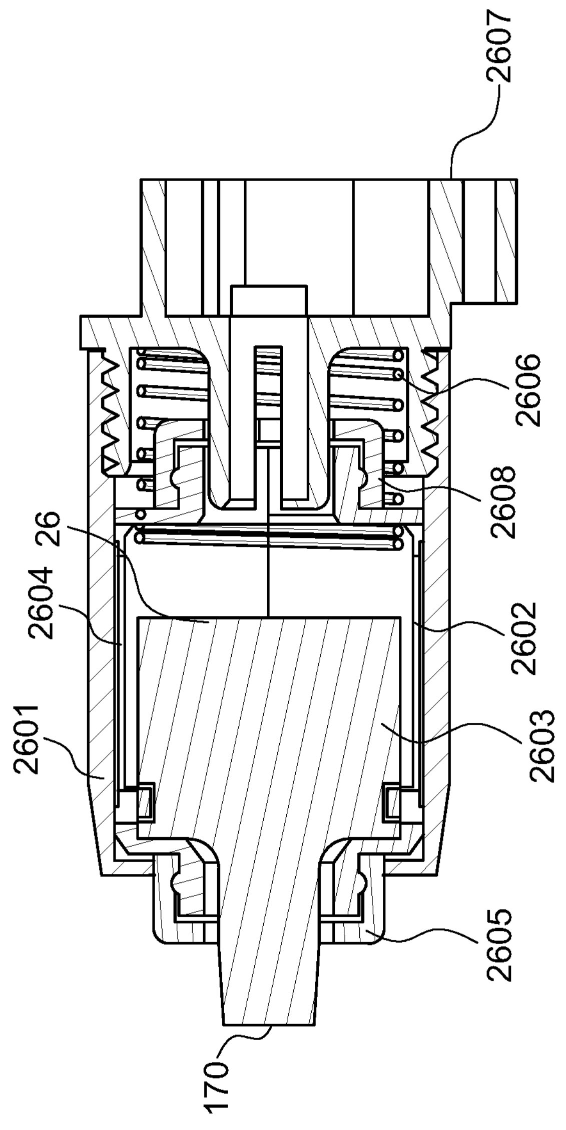

FIG. 31

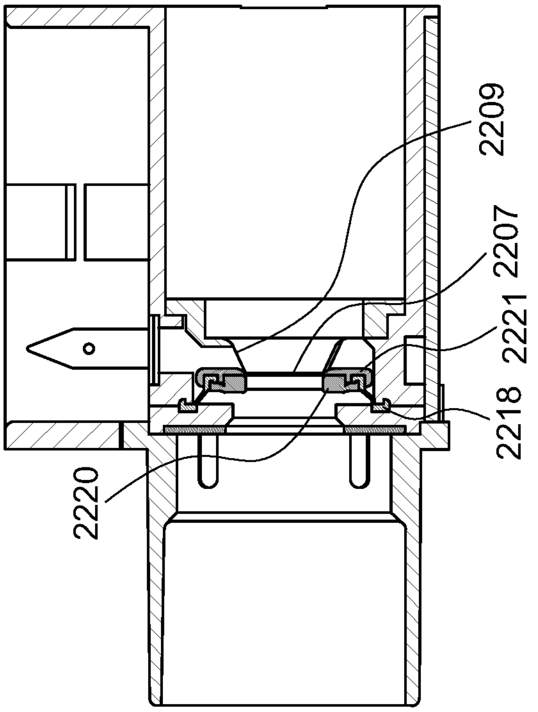

FIG. 33

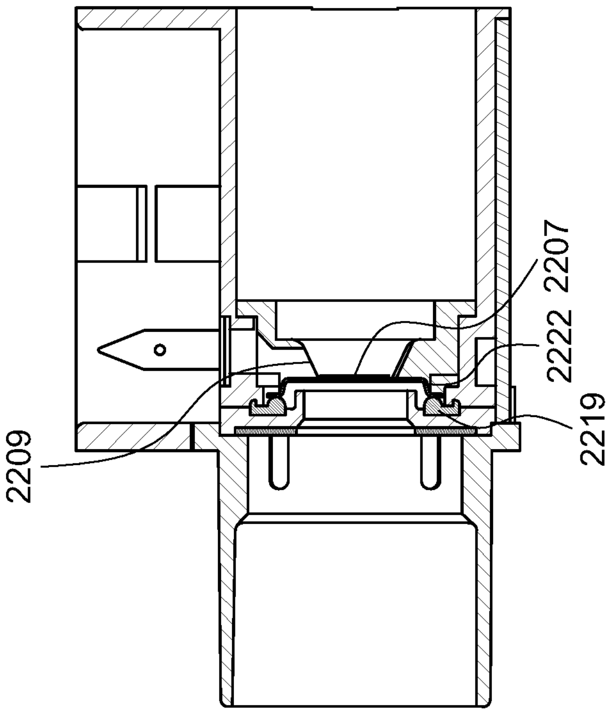

FIG. 32

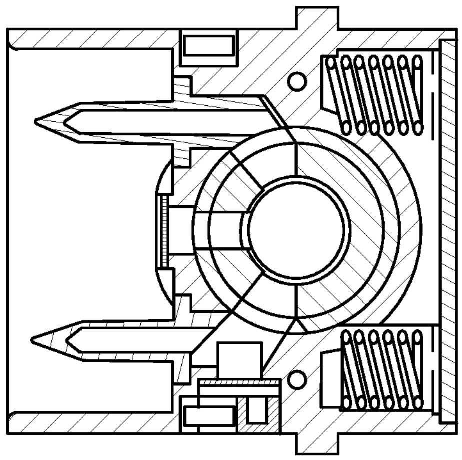

FIG. 34B

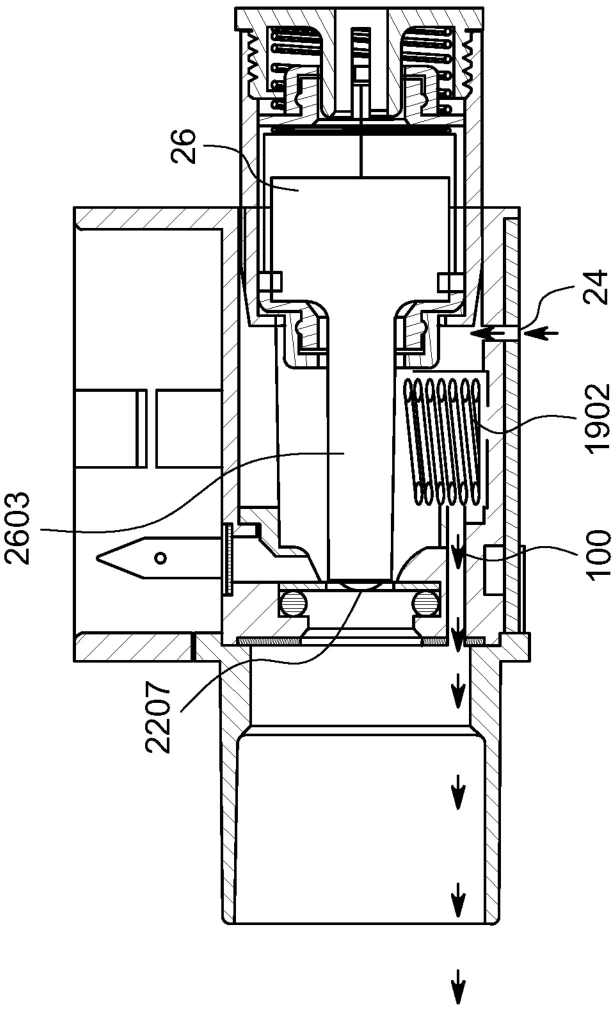

FIG. 34A

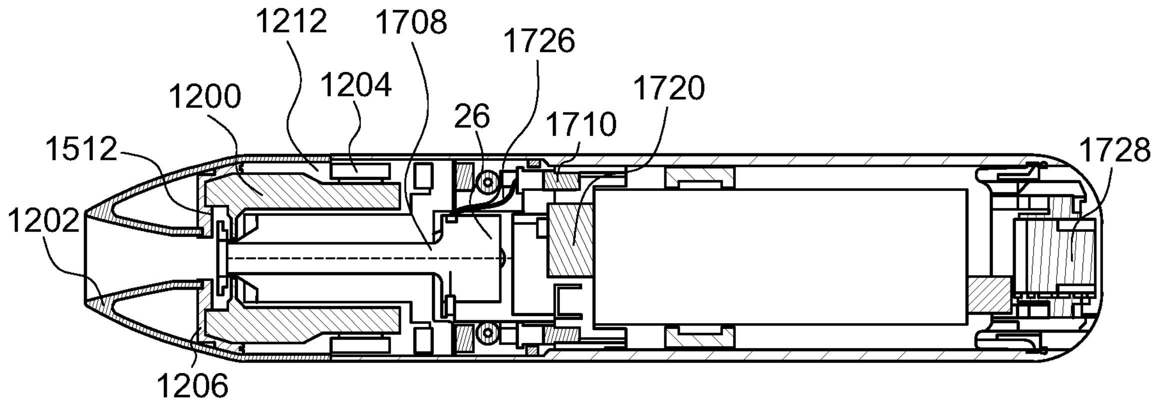

FIG. 35A

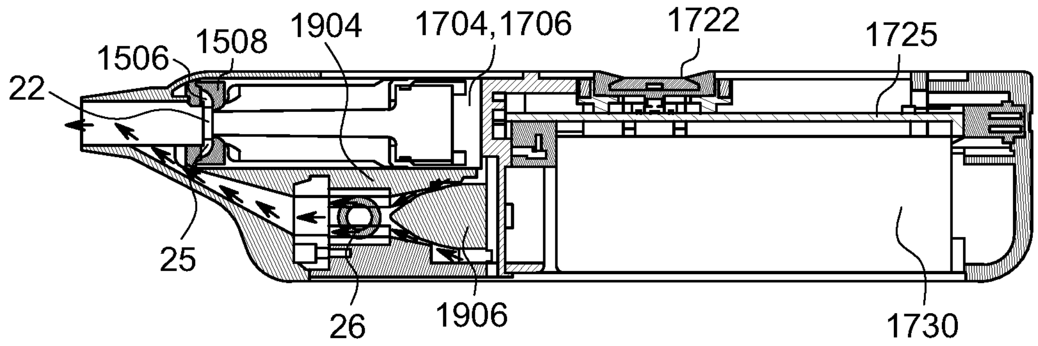

FIG. 35B

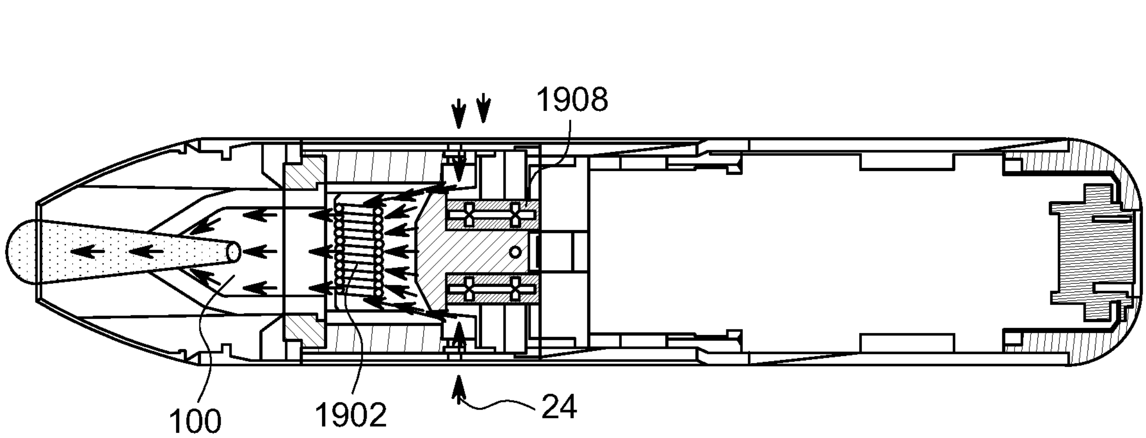

FIG. 35C

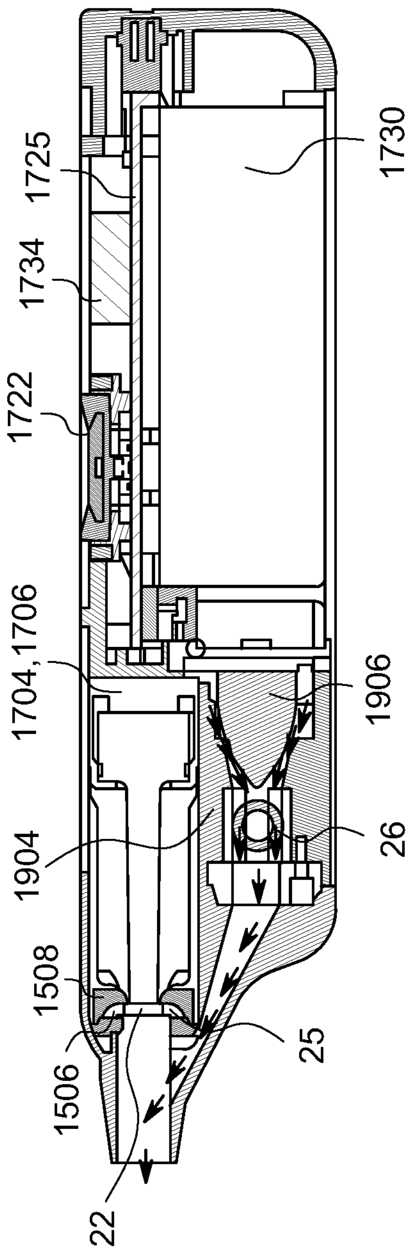

FIG. 36

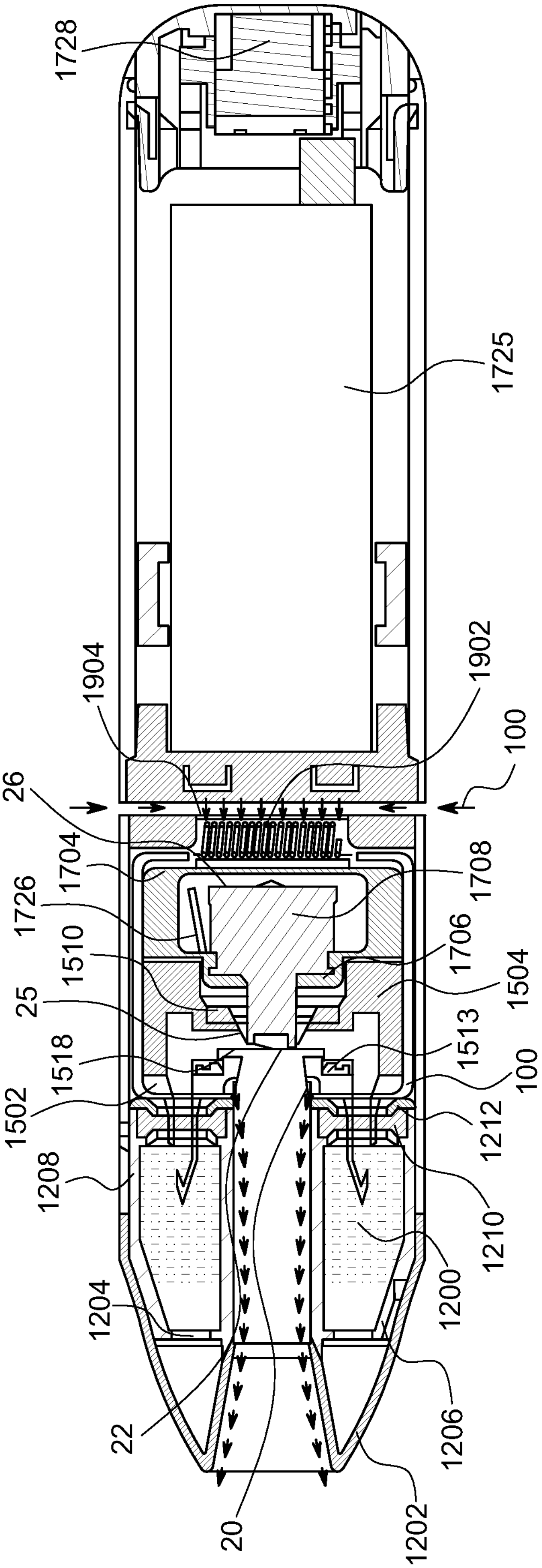
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FIG. 37

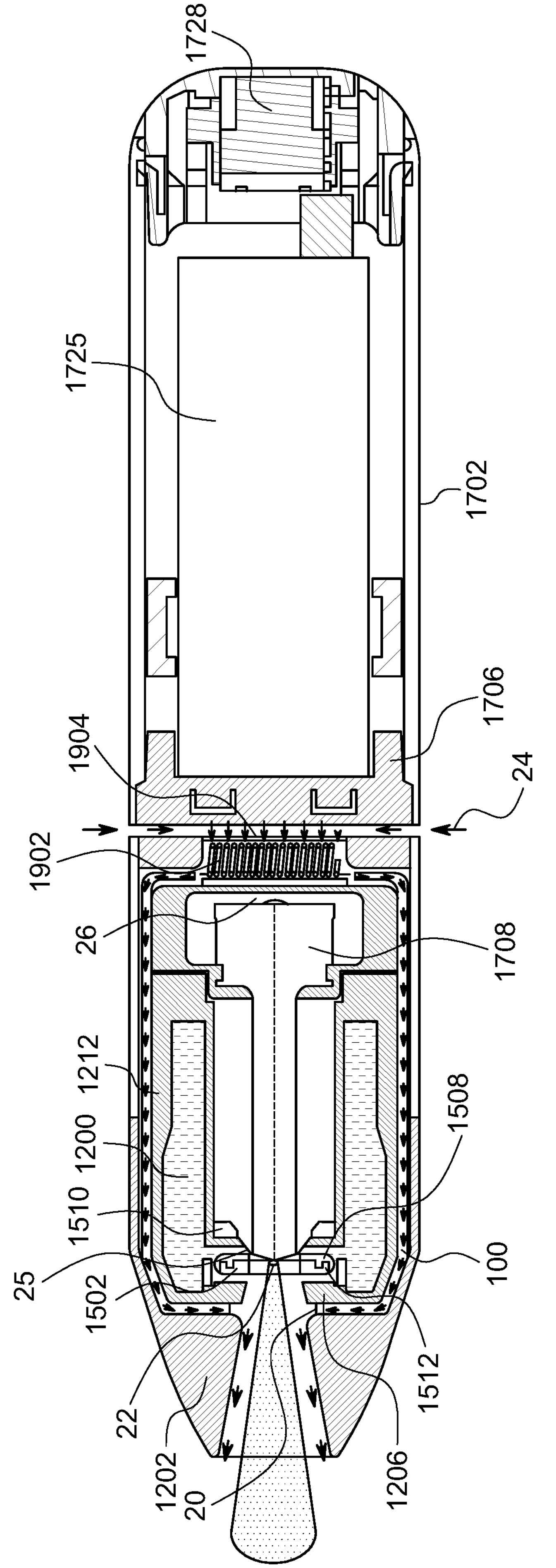
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FIG. 38

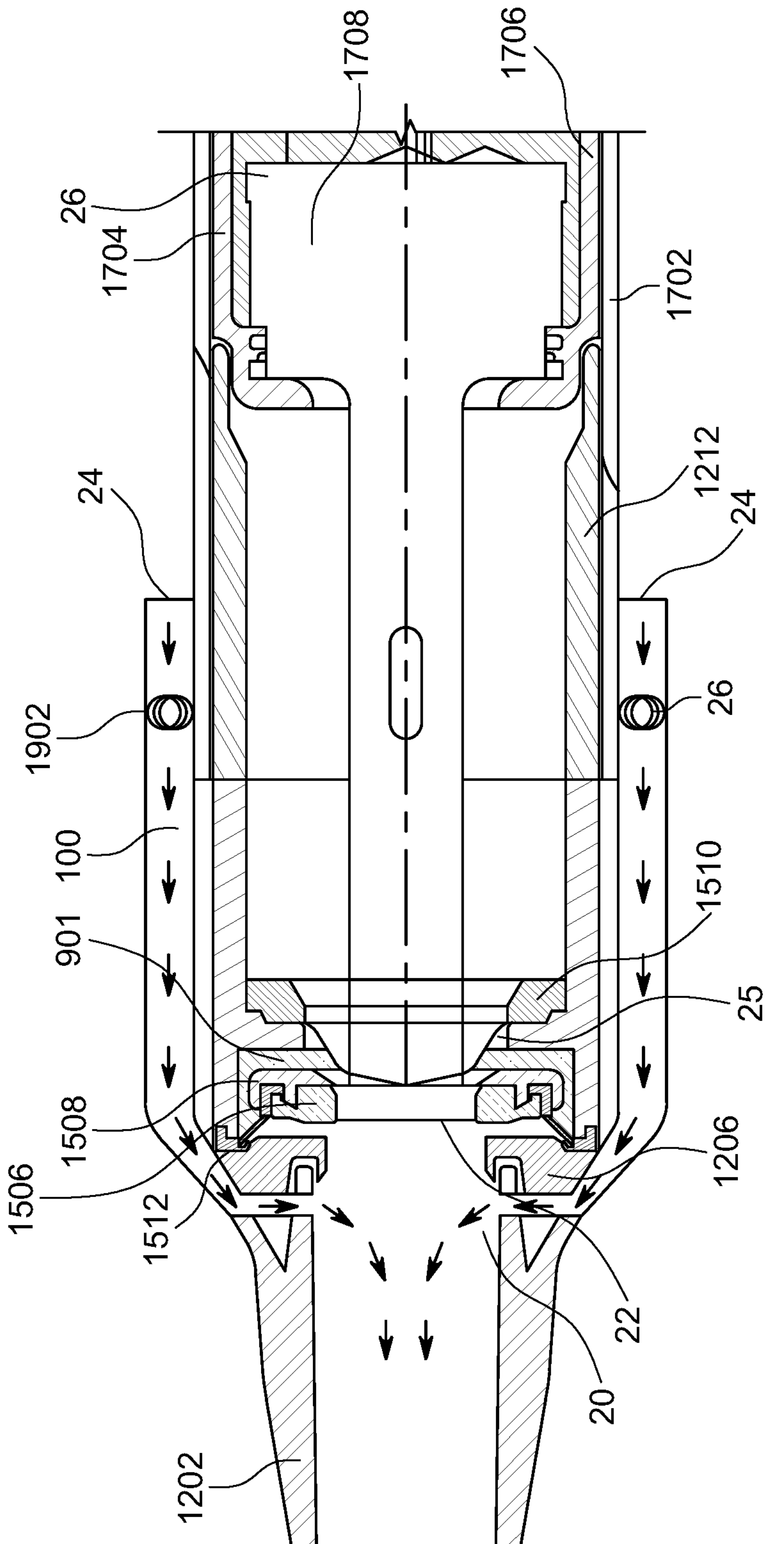
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FIG. 39

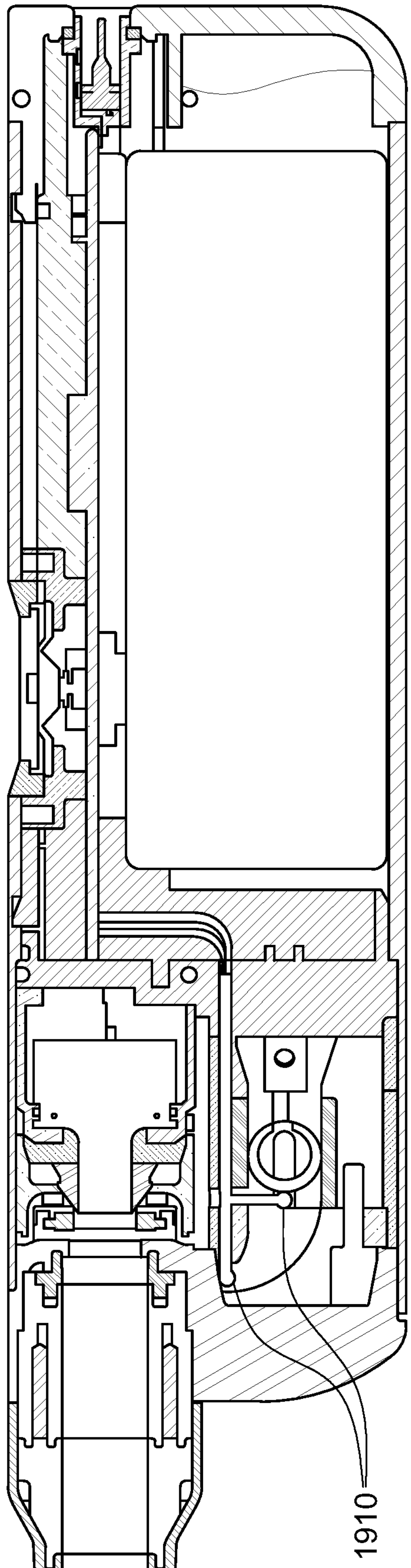


FIG. 40

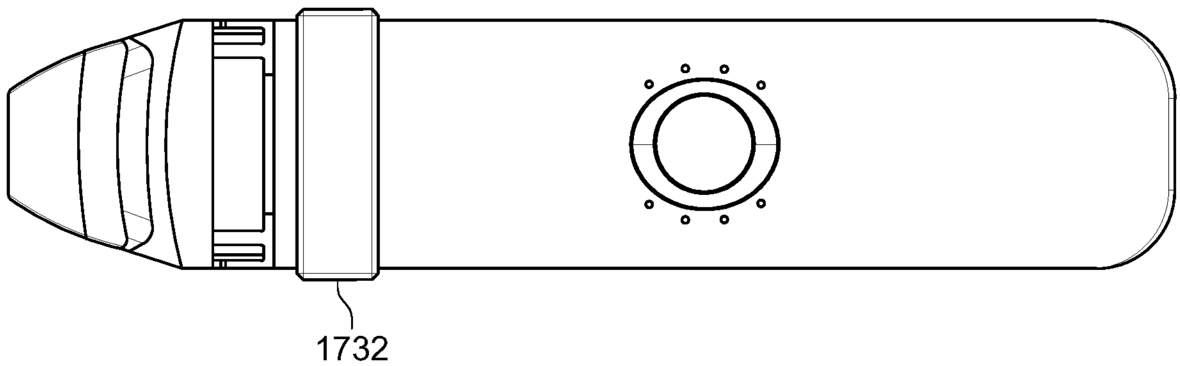


FIG. 41A

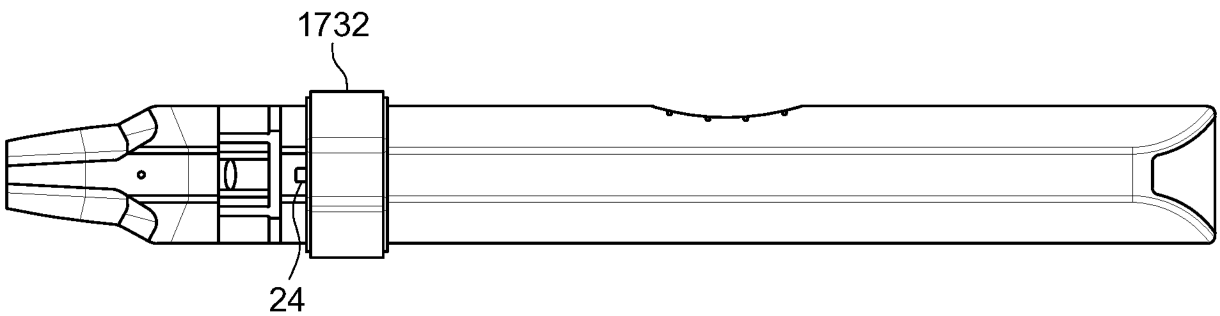


FIG. 41B

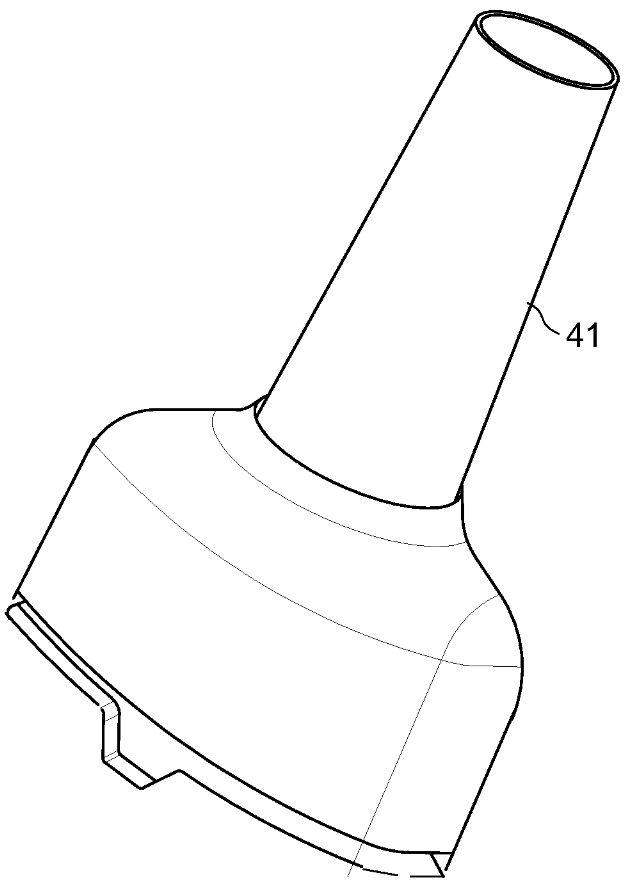


FIG. 42

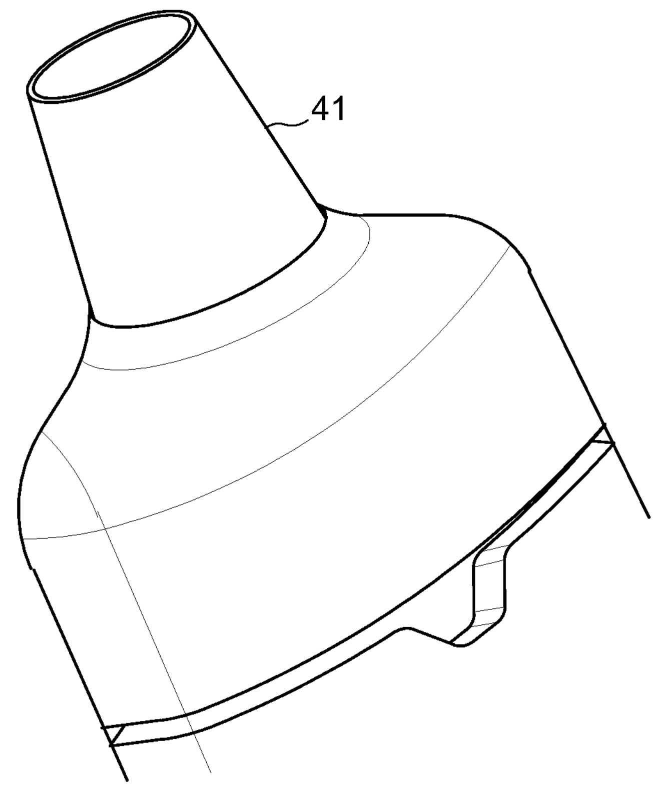


FIG. 43

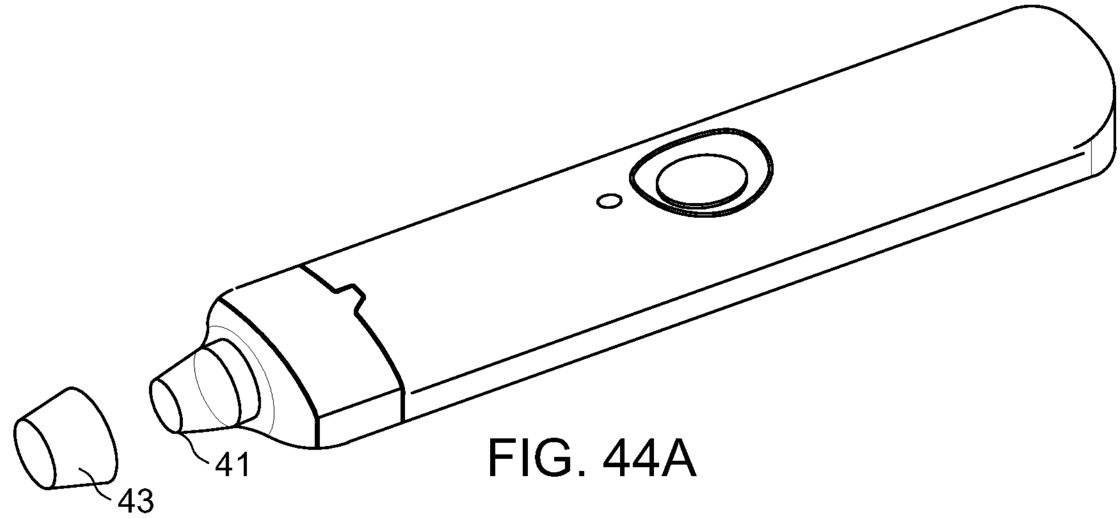


FIG. 44A

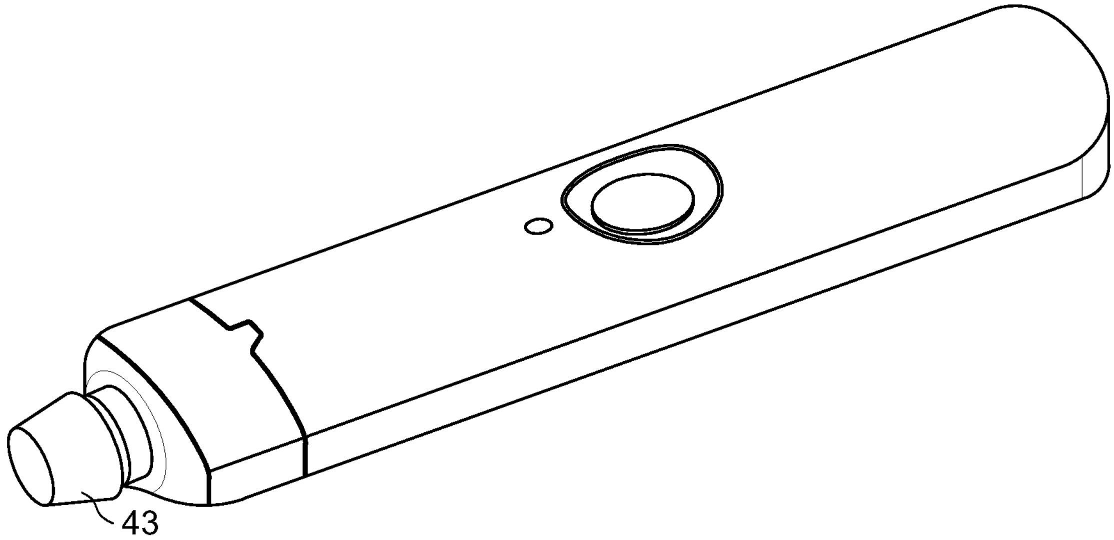


FIG. 44B

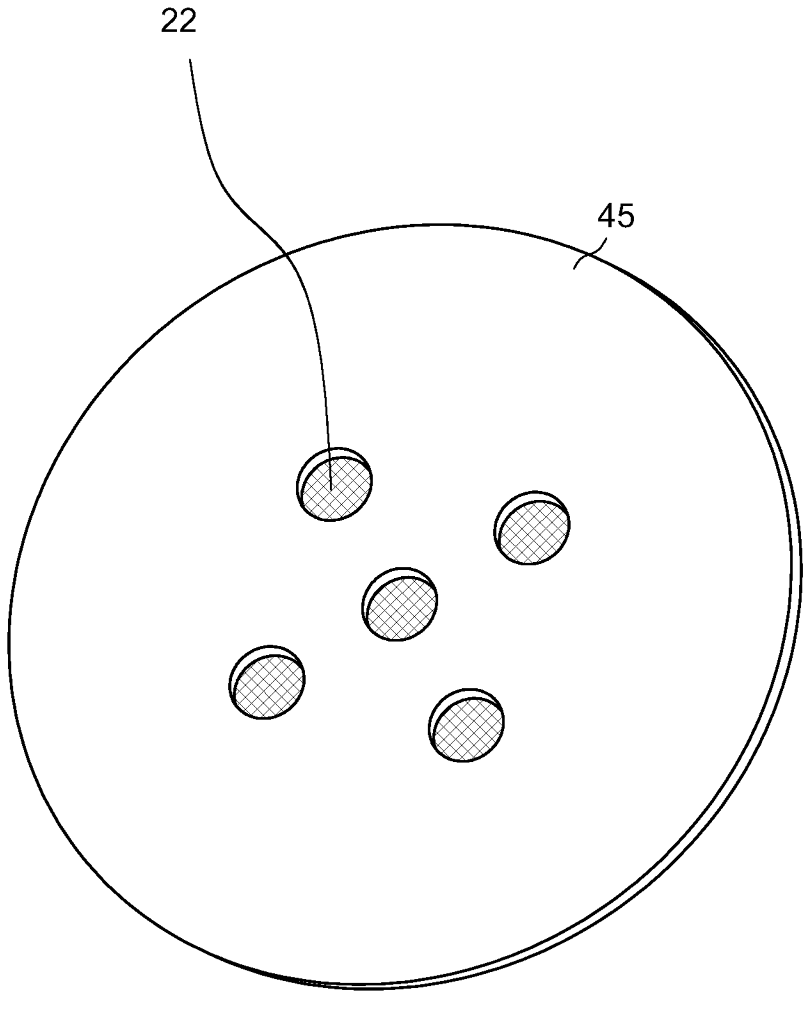


FIG. 45

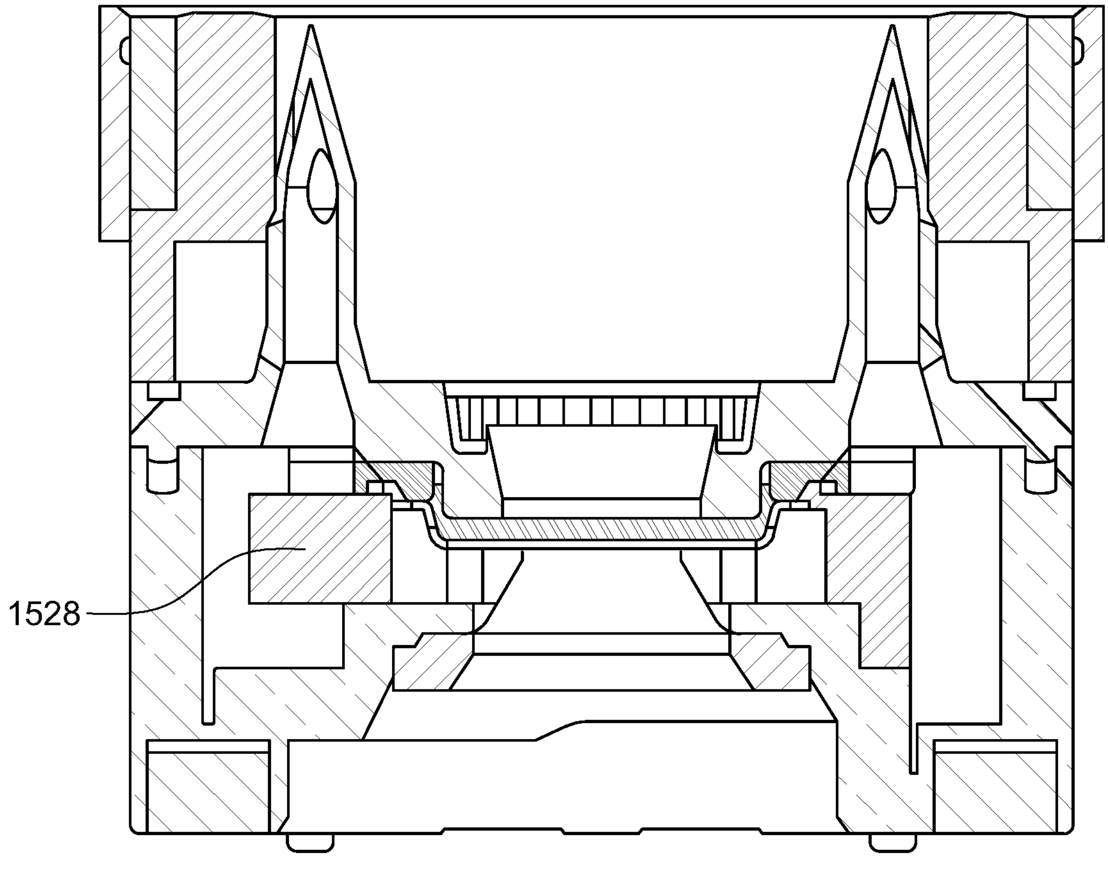


FIG. 46

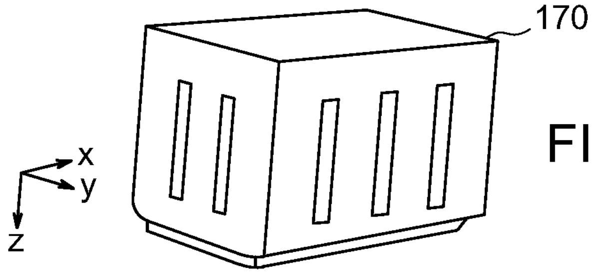


FIG. 47A

(a) Structure diagram of the vibrating member tip

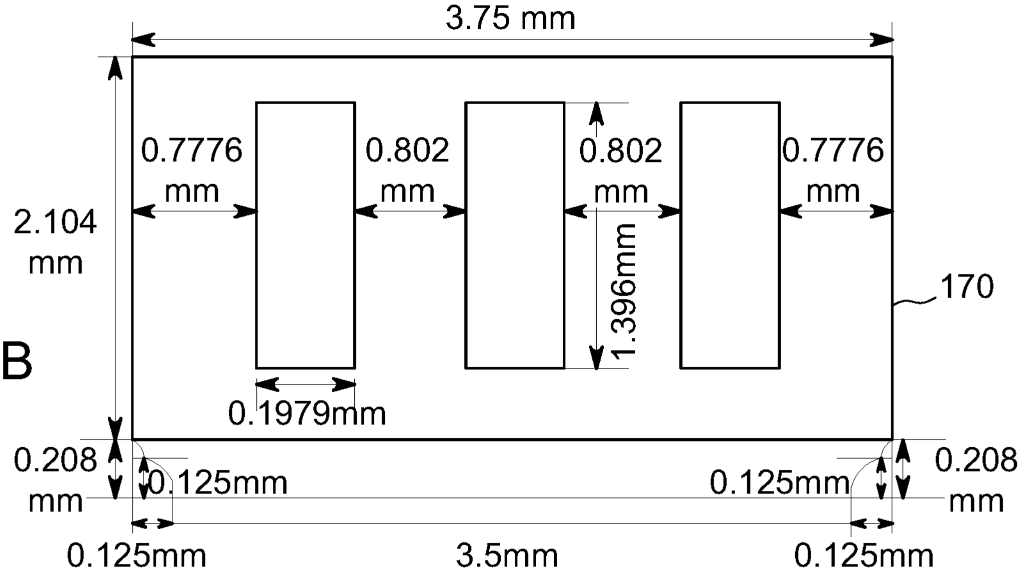


FIG. 47B

(b) Dimensional drawing of vibrating member tip on the XZ surface

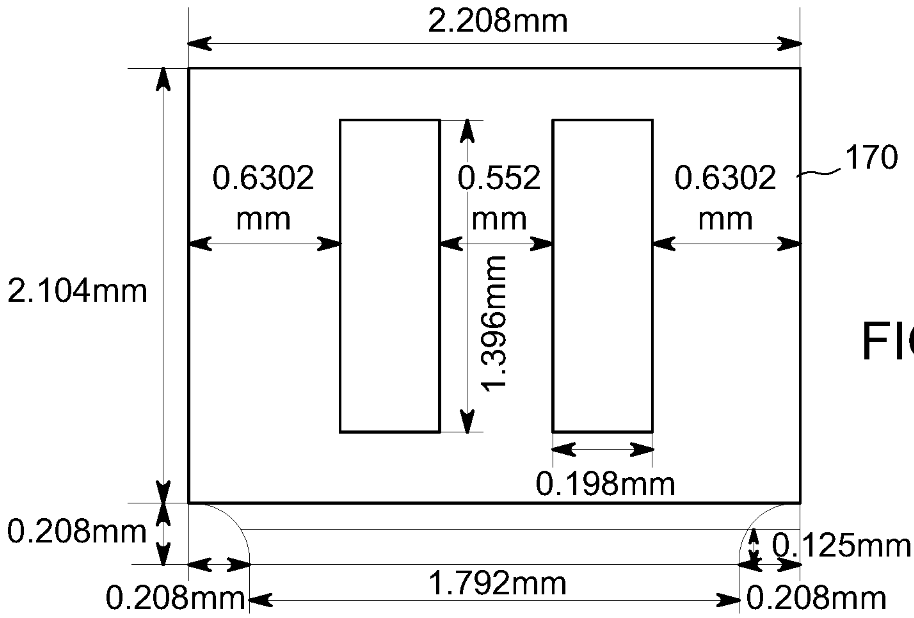


FIG. 47C

(c) Dimensional drawing of vibrating member tip on the YZ surface

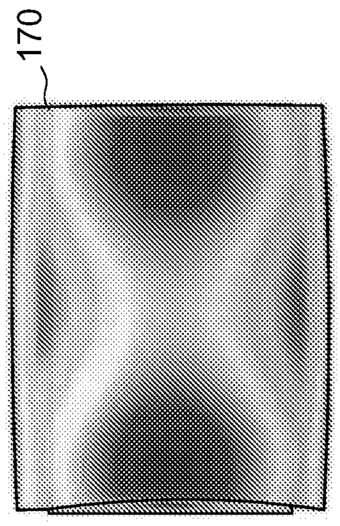


FIG. 48C

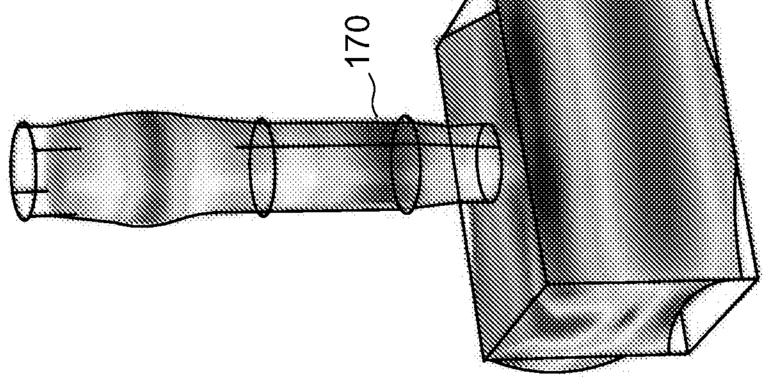


FIG. 48B

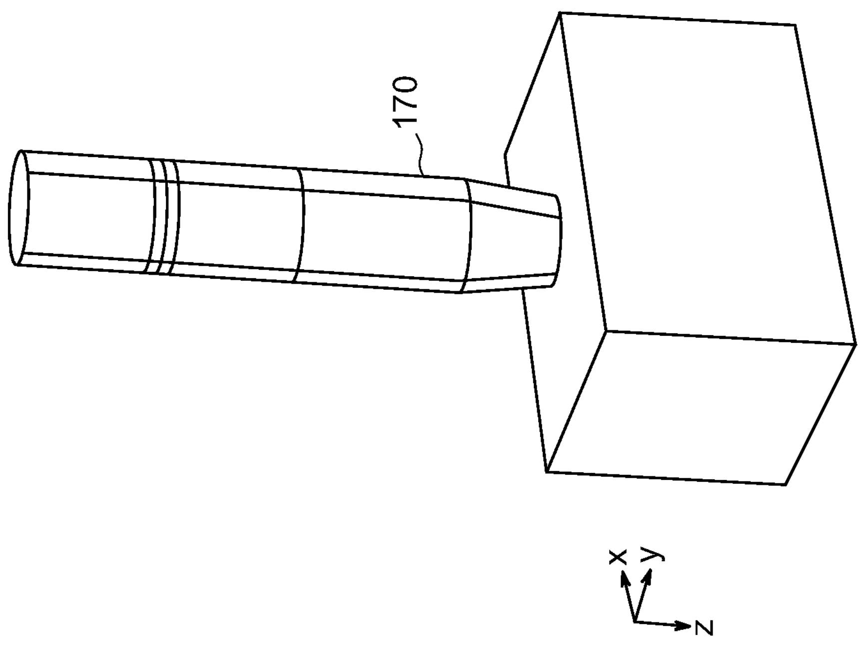


FIG. 48A

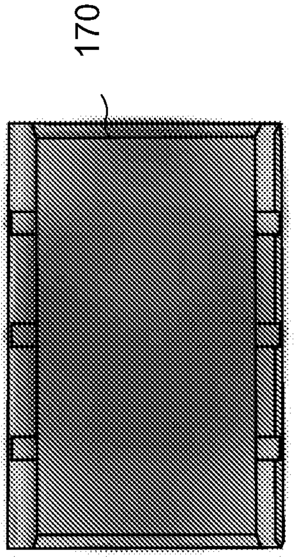


FIG. 49C

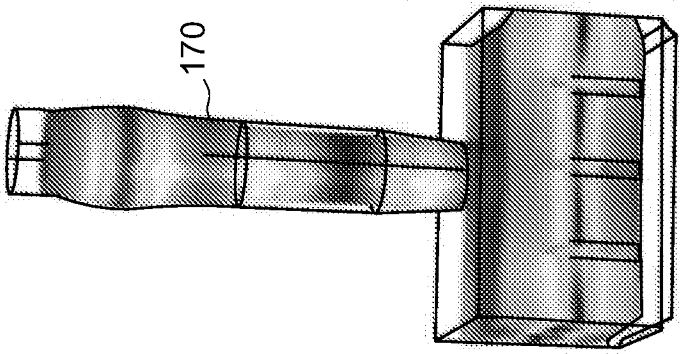


FIG. 49B

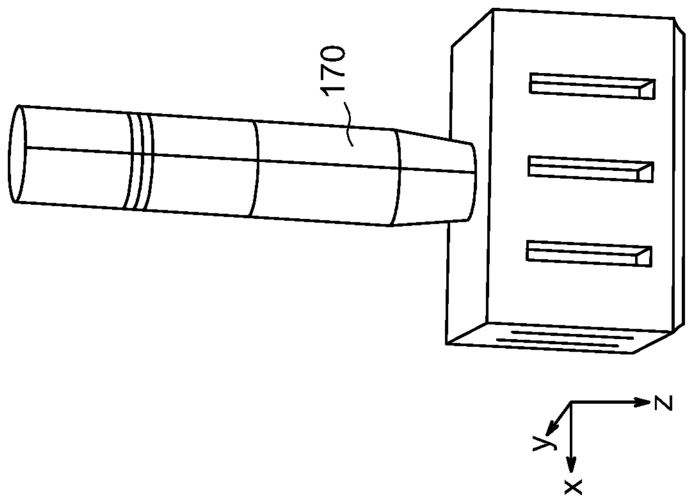


FIG. 49A

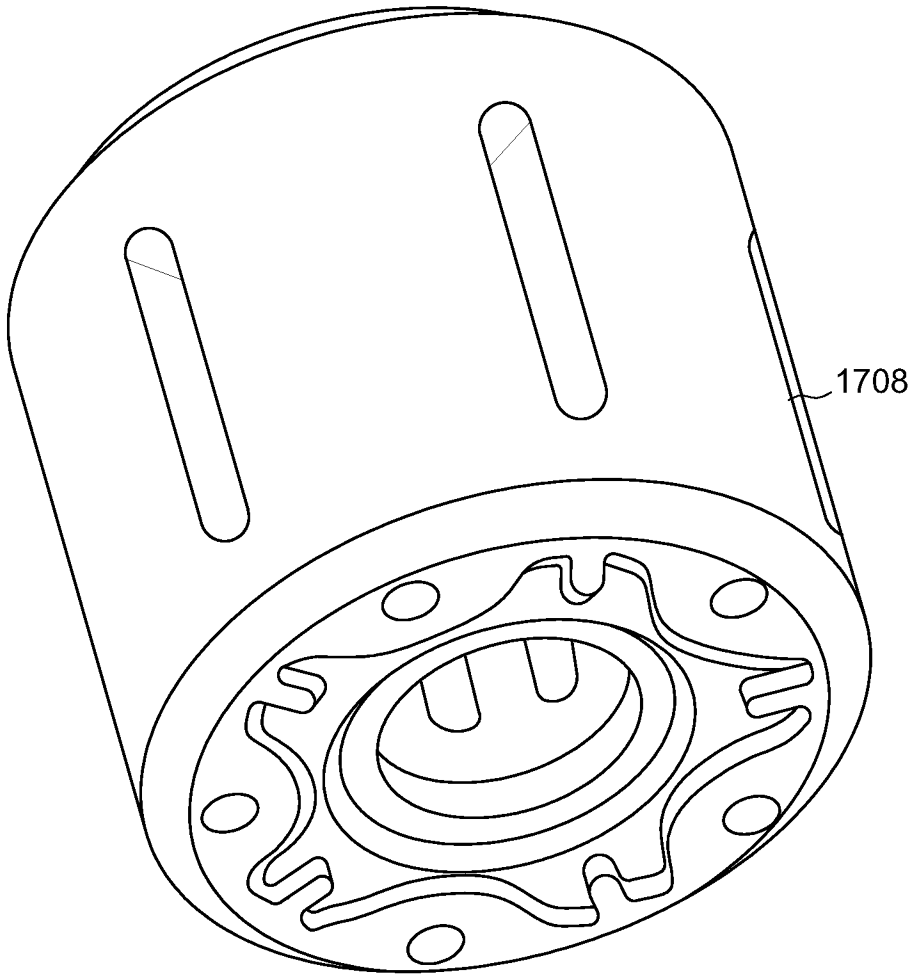


FIG. 50

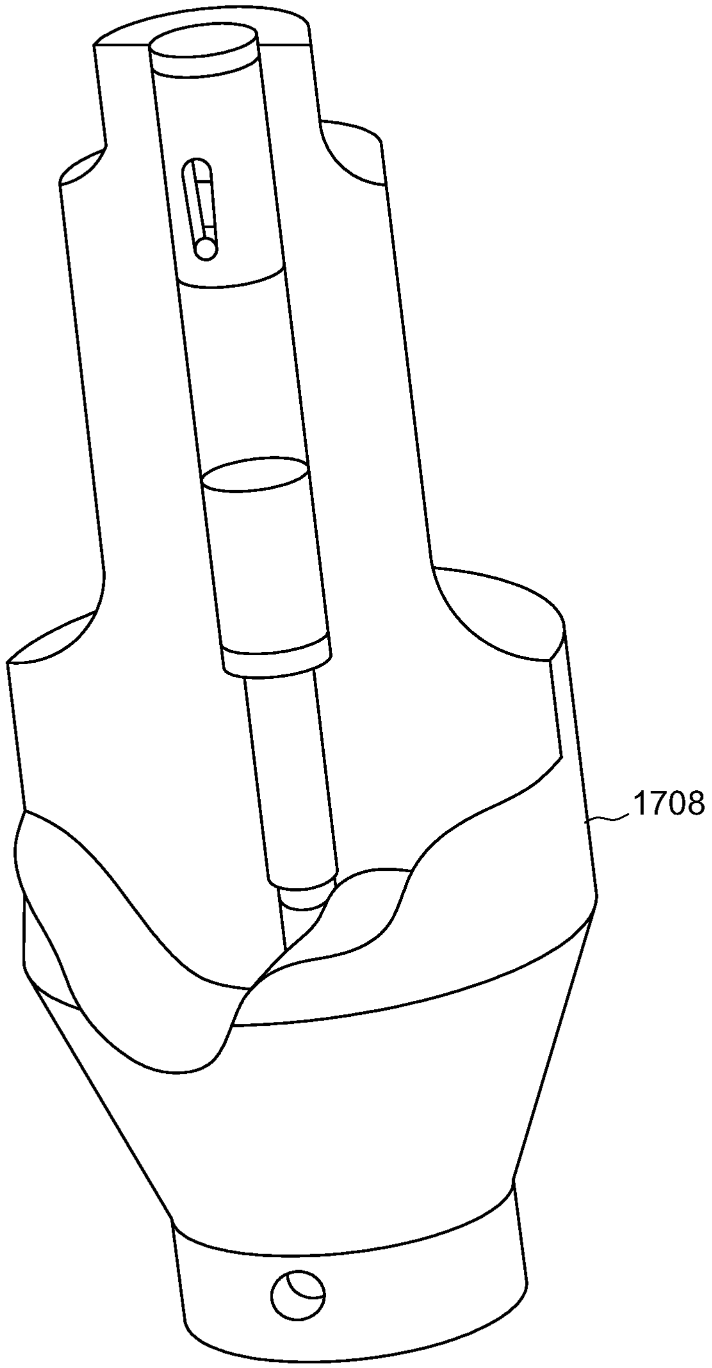


FIG. 51

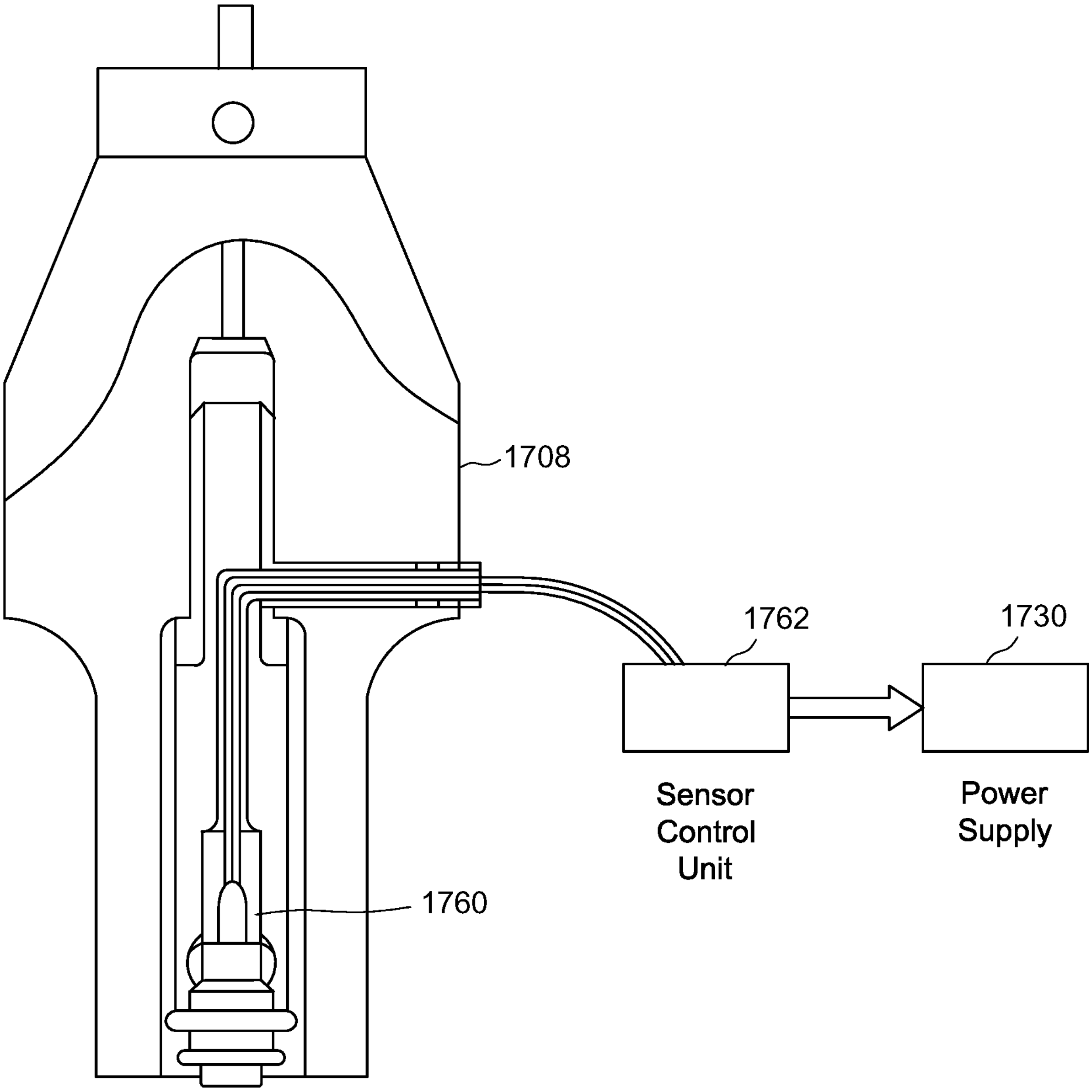


FIG. 52

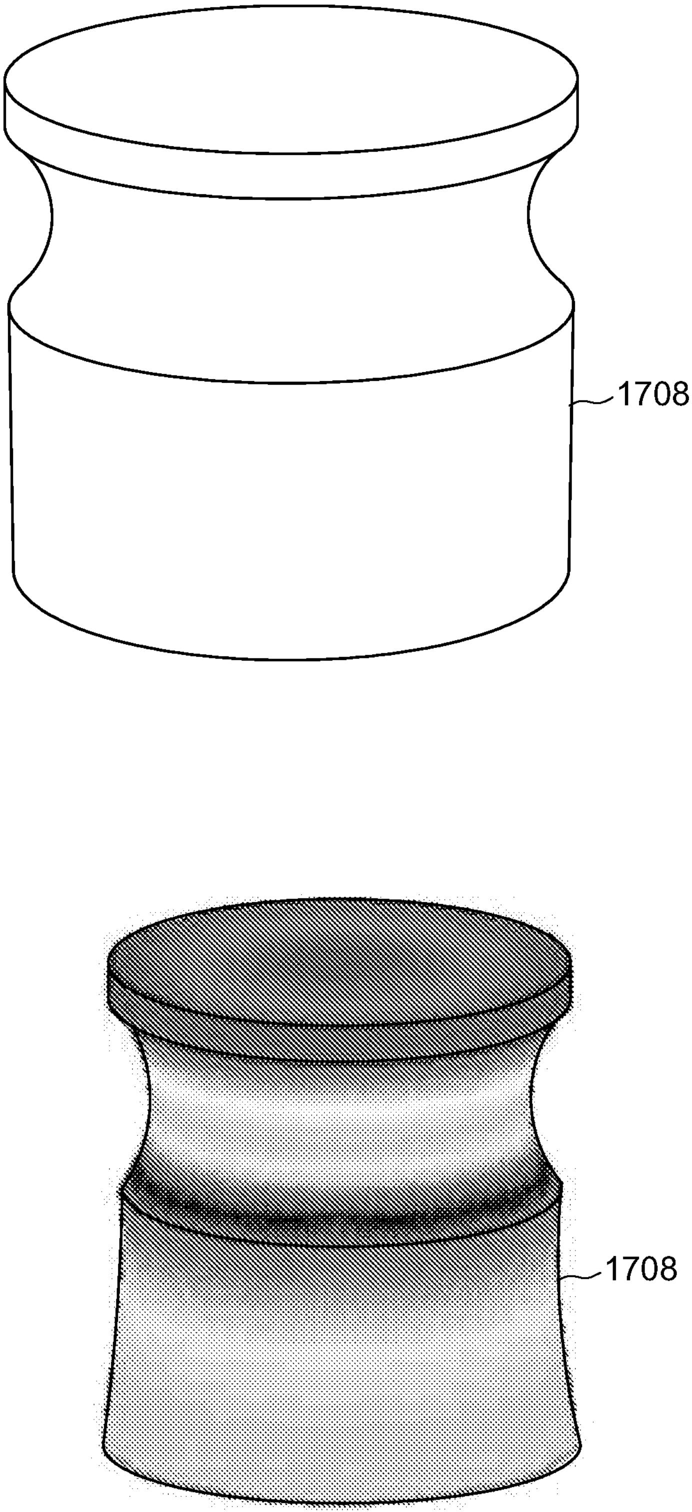
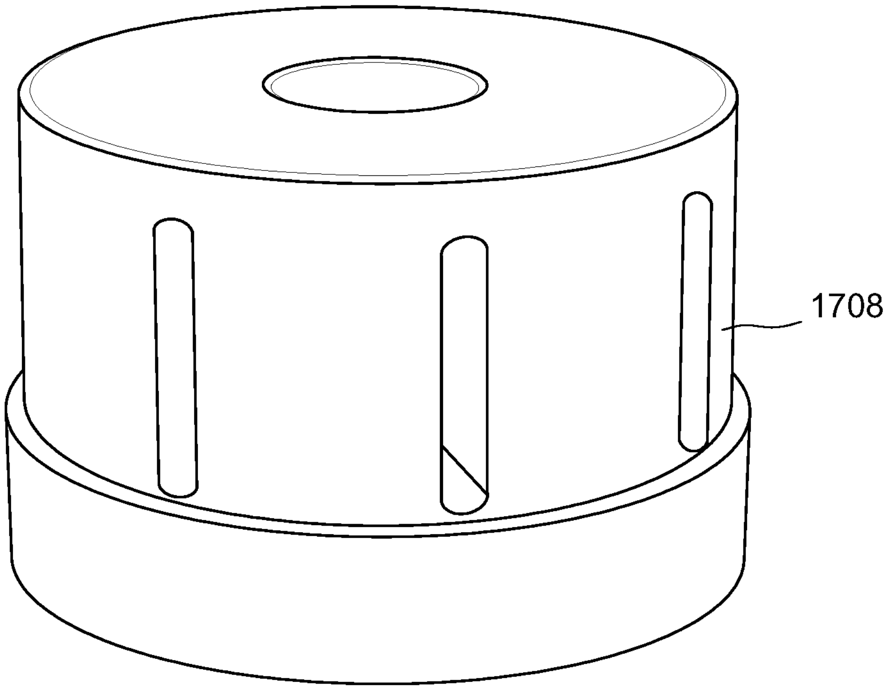


FIG. 53

FIG. 54A



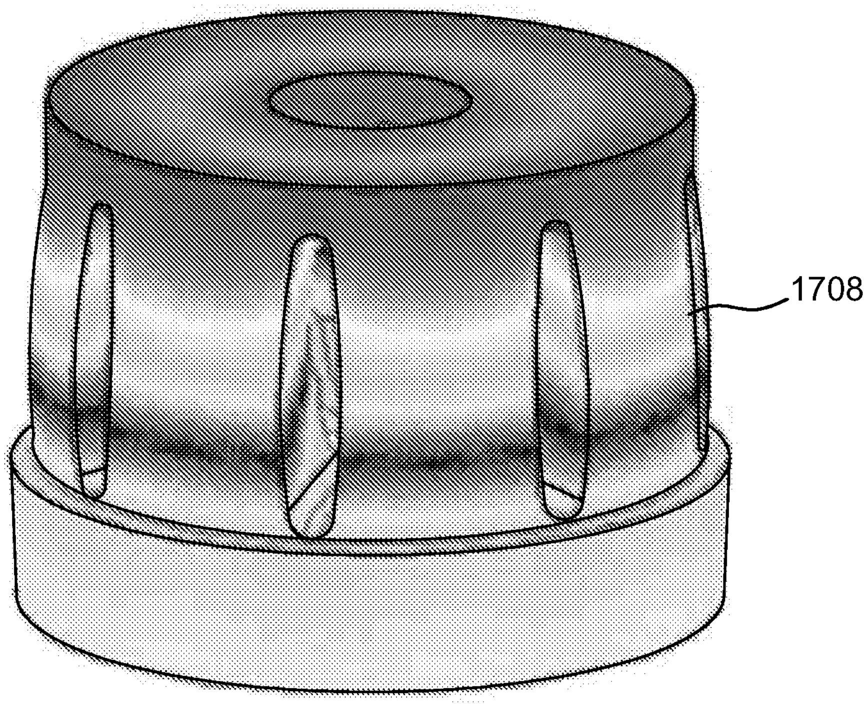


FIG. 54B

FIG. 55A

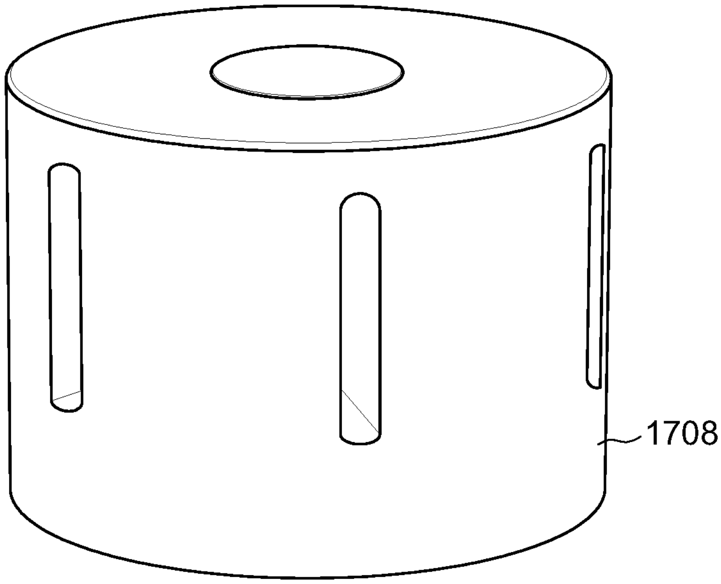
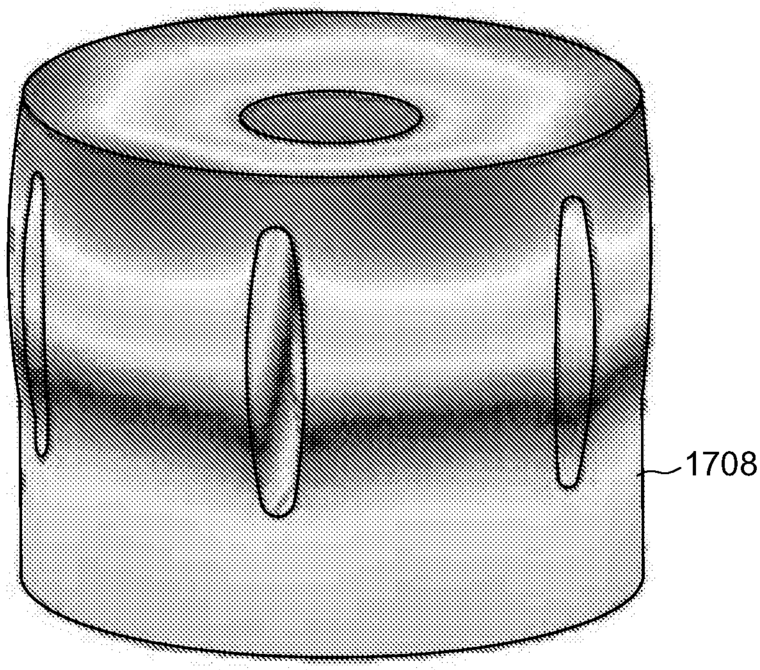


FIG. 55B



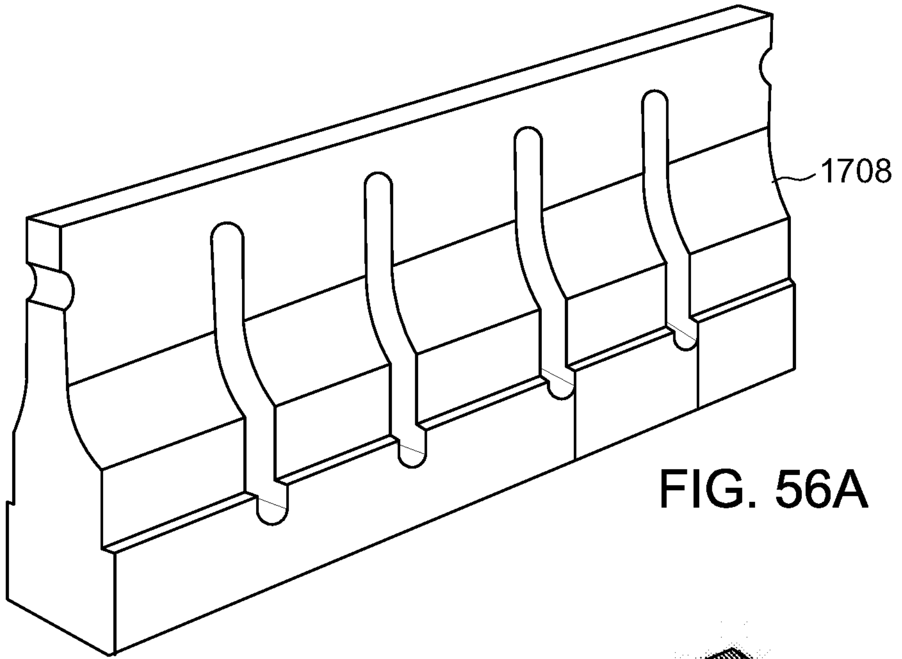


FIG. 56A

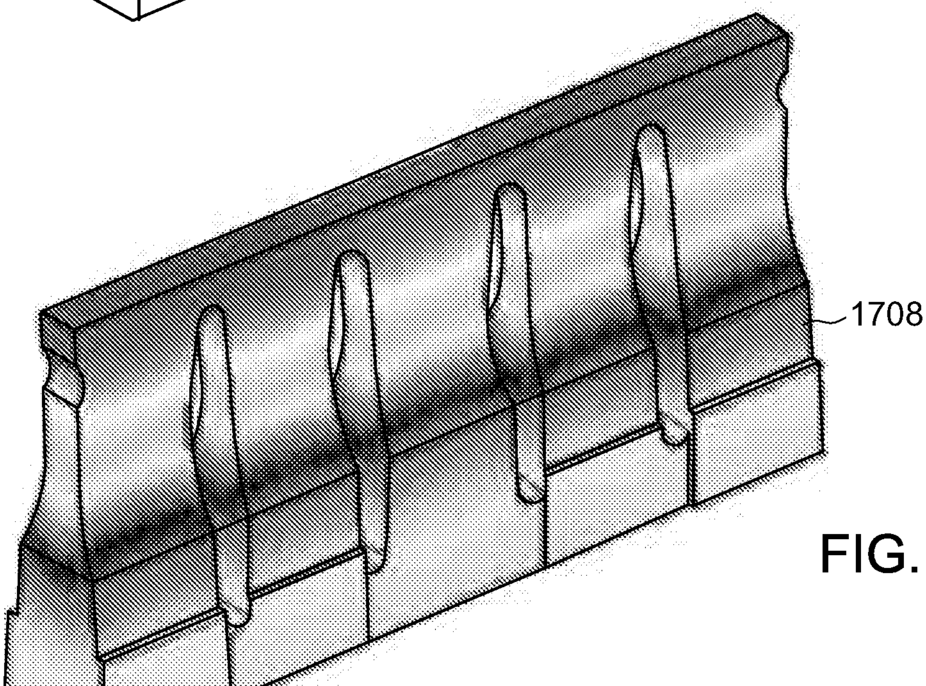


FIG. 56B

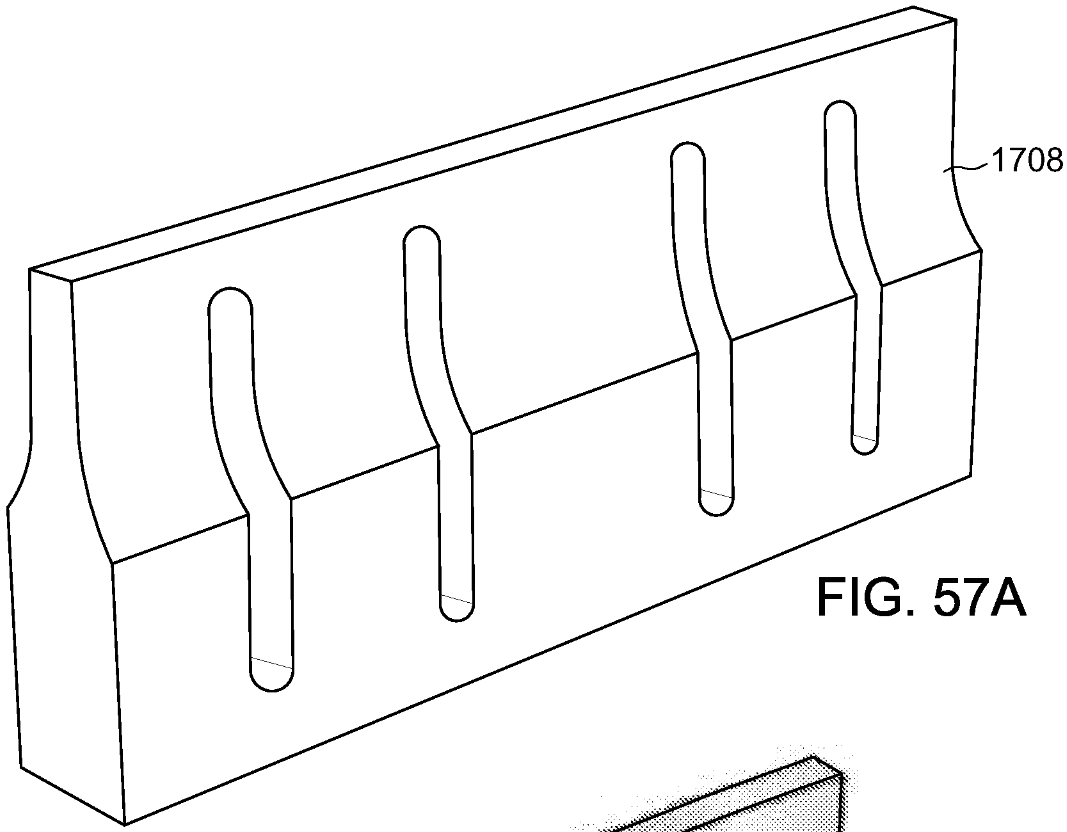


FIG. 57A

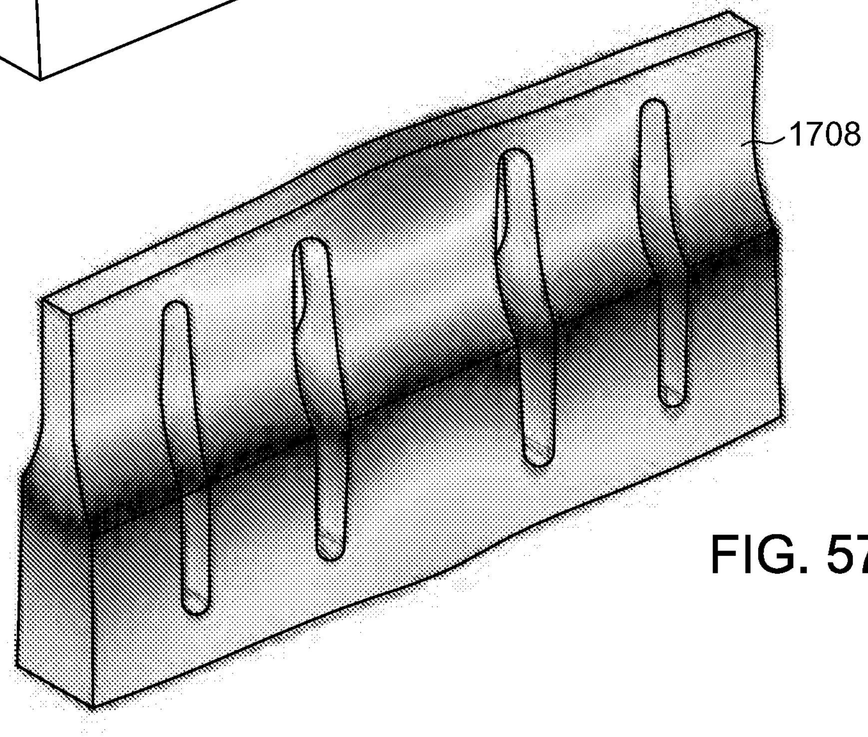


FIG. 57B

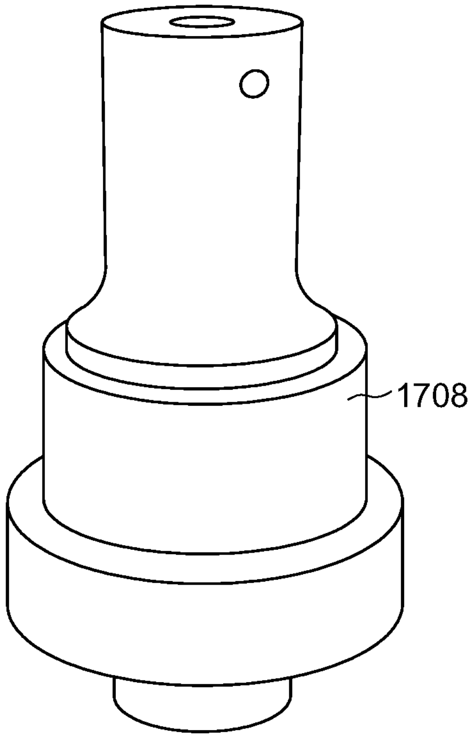


FIG. 58A

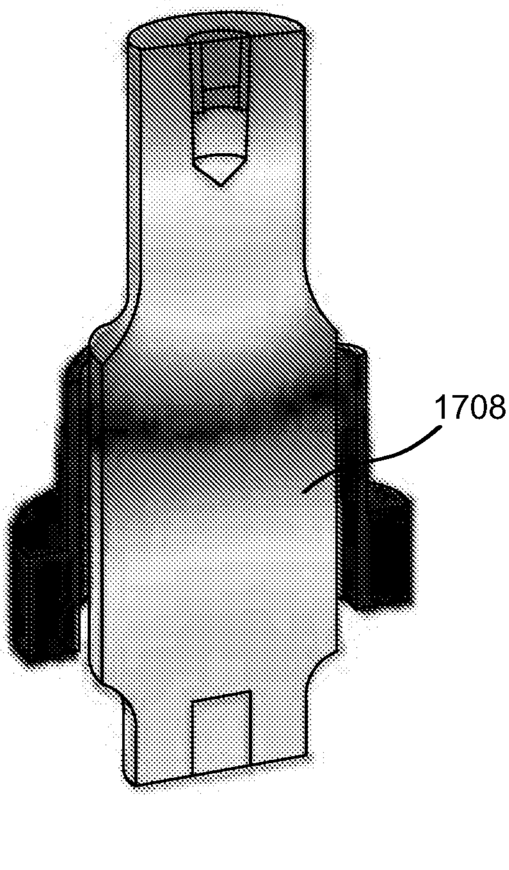


FIG. 58B

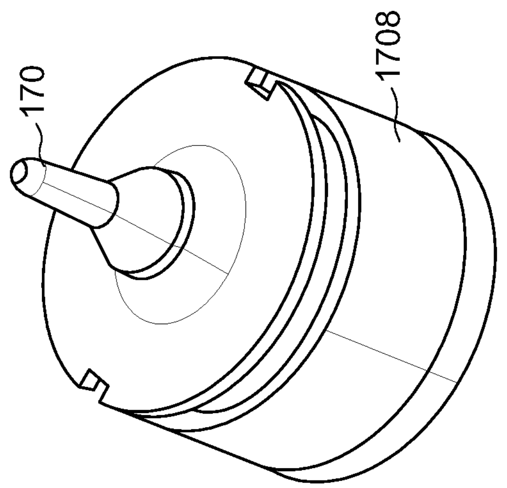


FIG. 59A

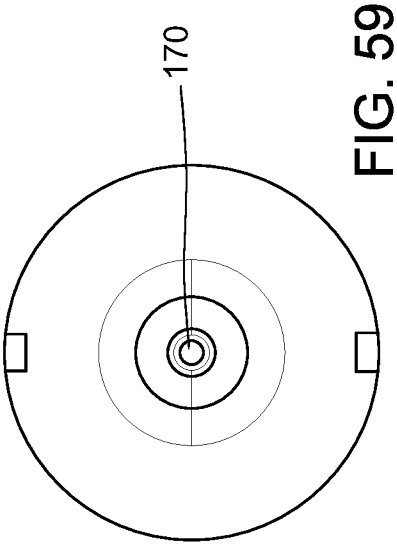


FIG. 59B

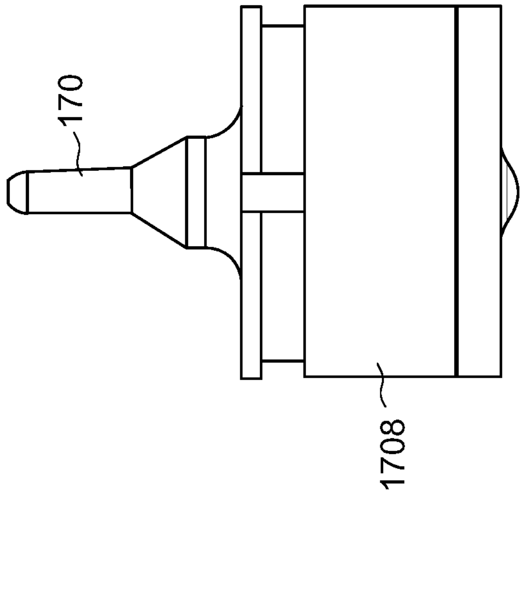


FIG. 59C

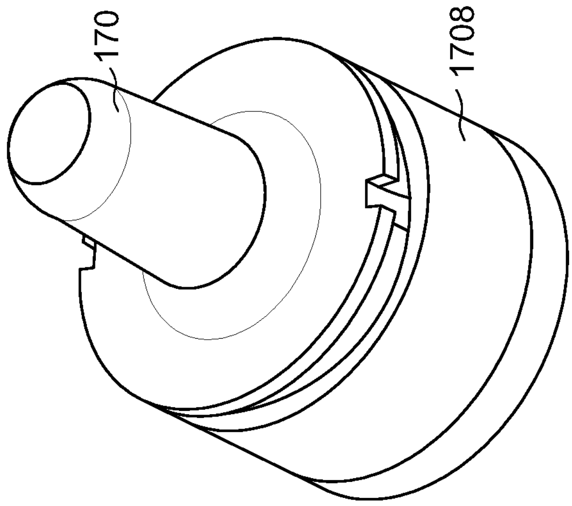


FIG. 60A

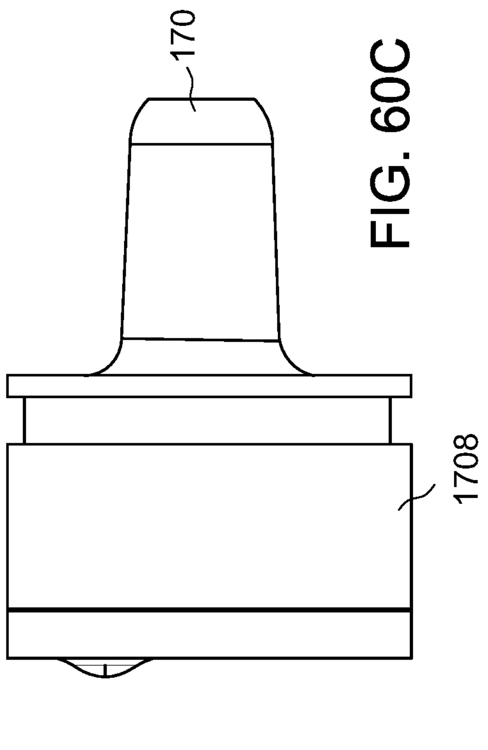


FIG. 60C

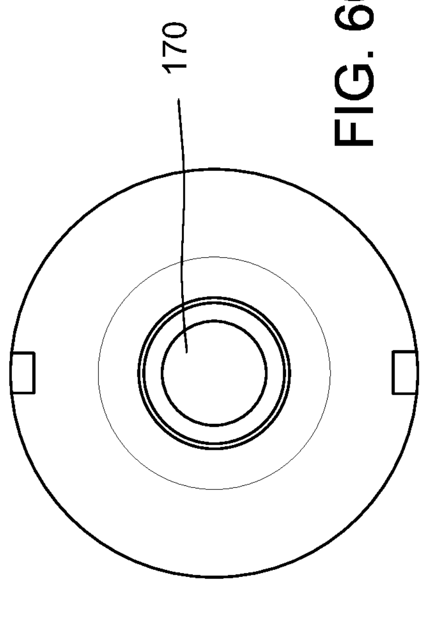


FIG. 60B

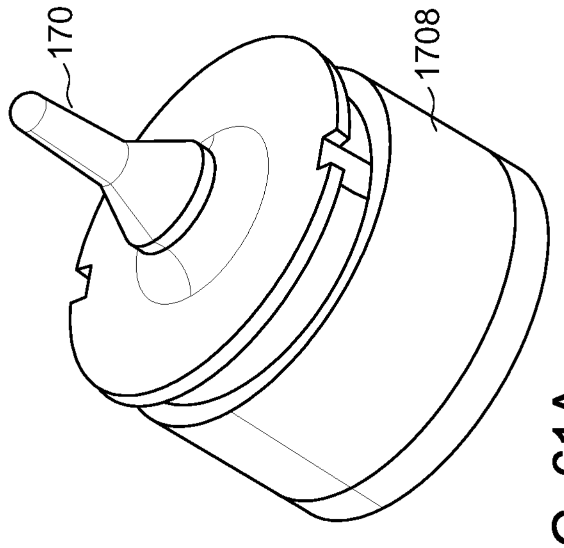


FIG. 61A

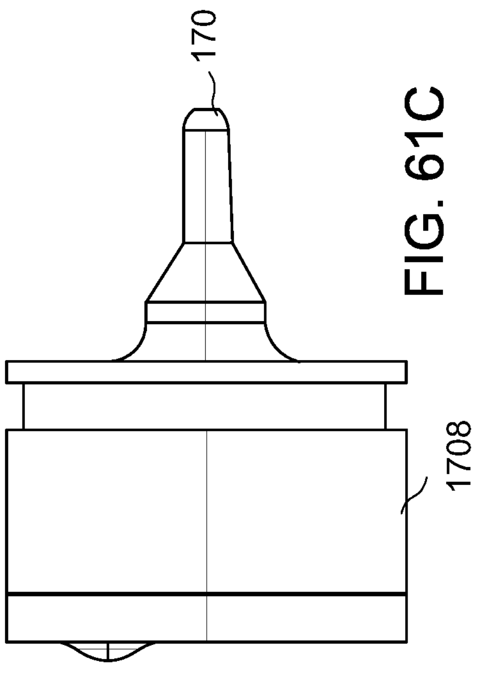


FIG. 61C

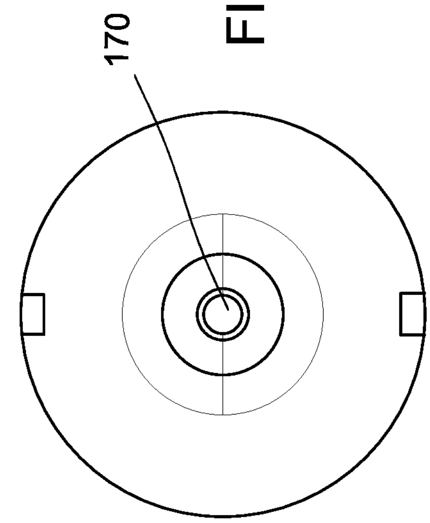


FIG. 61B

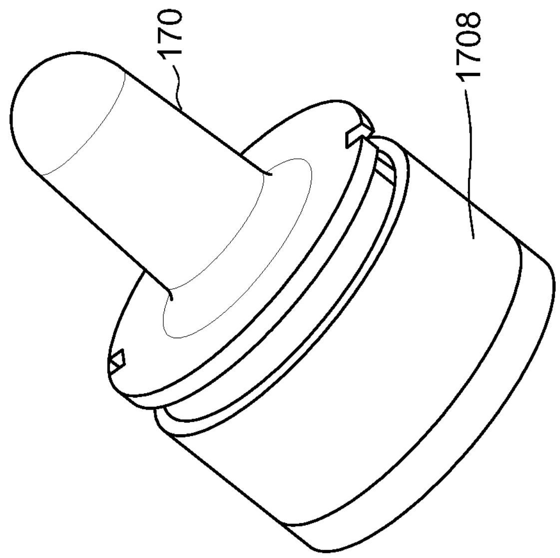


FIG. 62A

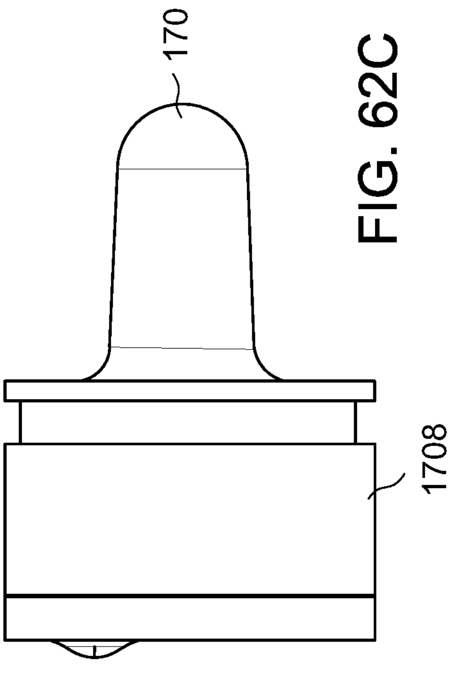


FIG. 62C

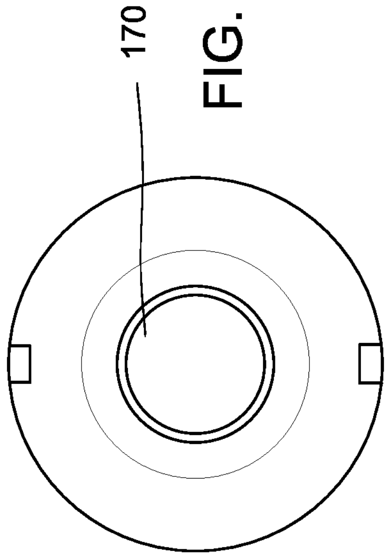


FIG. 62B

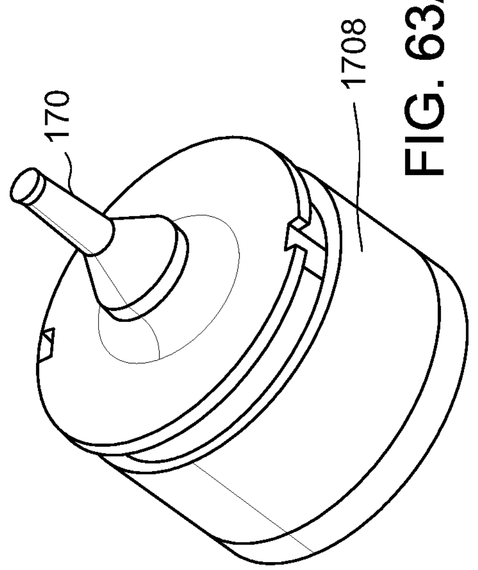


FIG. 63A

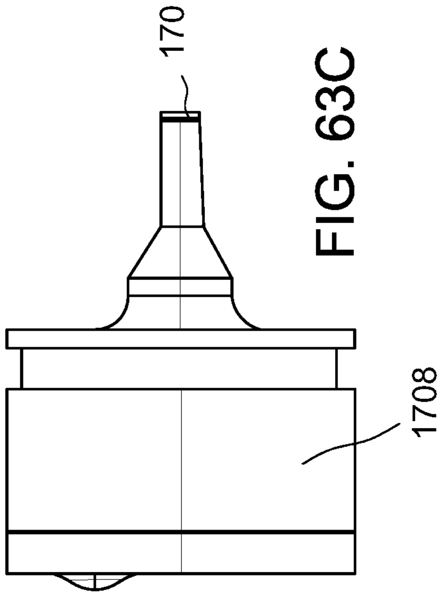


FIG. 63C

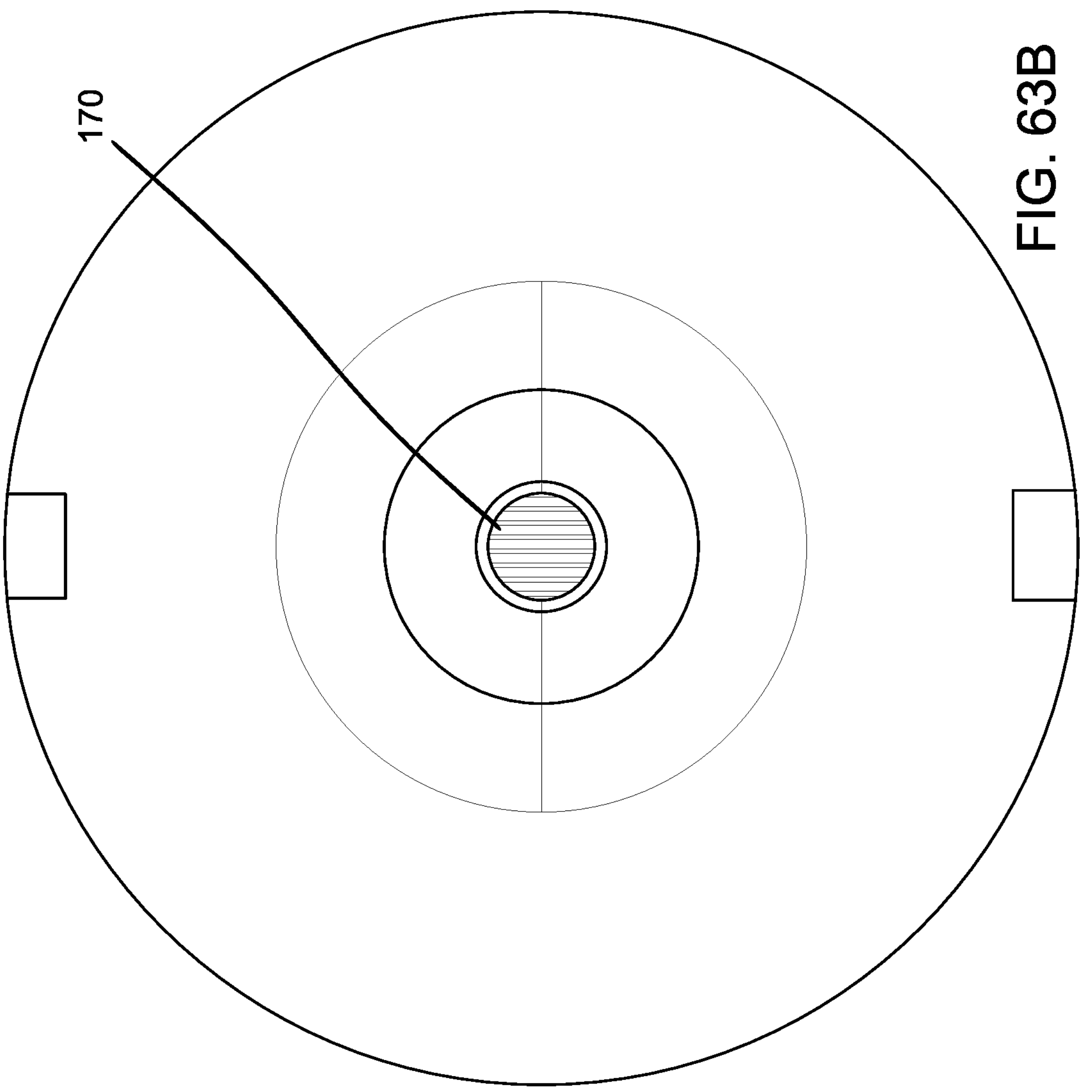


FIG. 63B

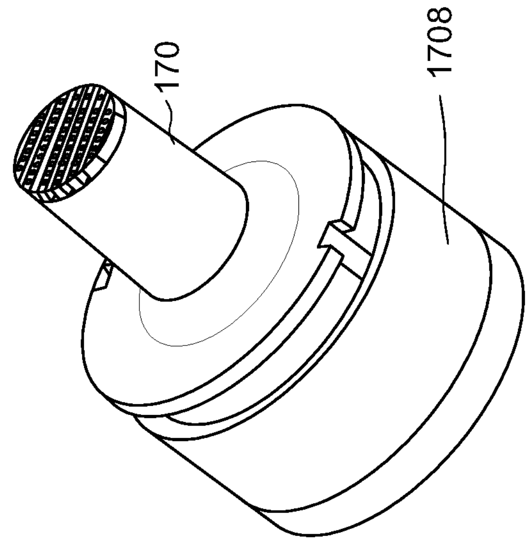


FIG. 64A

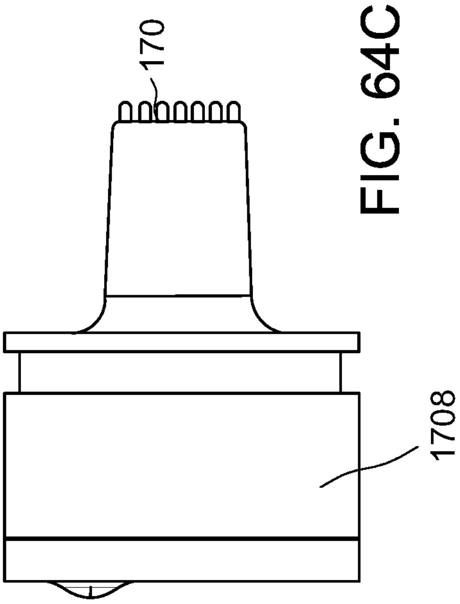


FIG. 64C

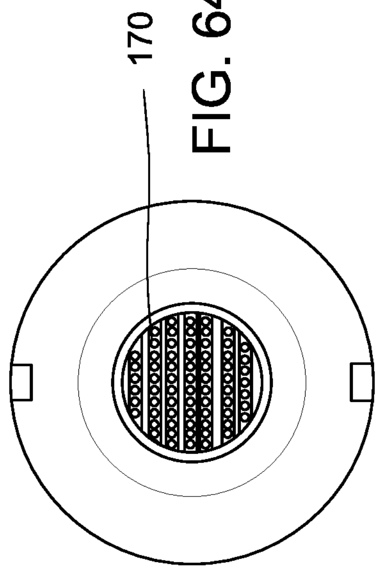


FIG. 64B

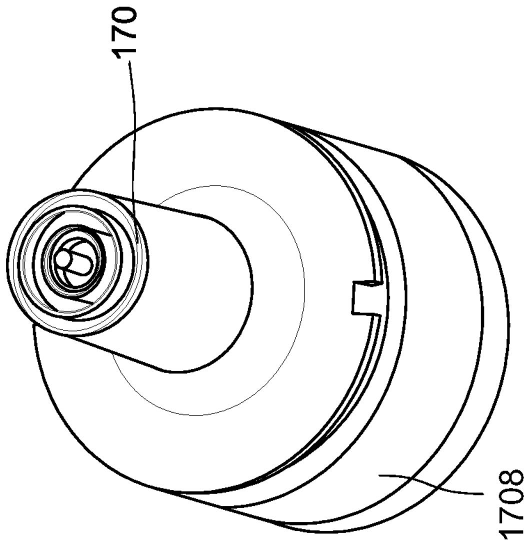


FIG. 65A

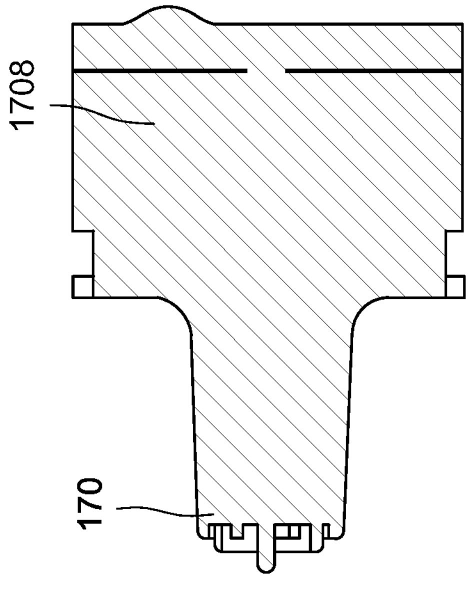


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FIG. 65D

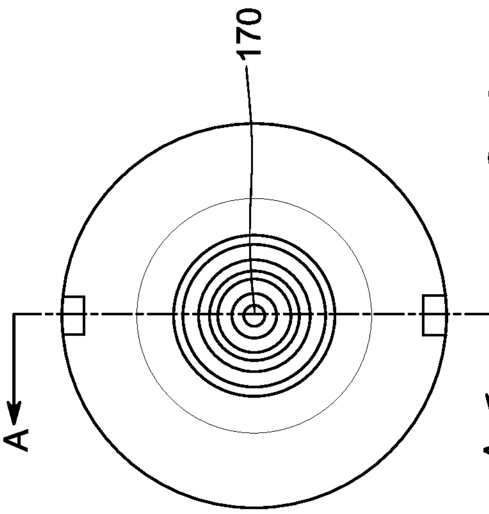


FIG. 65B

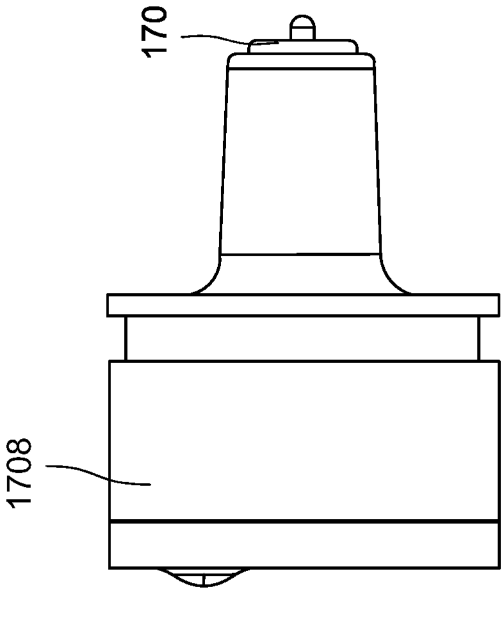


FIG. 65C

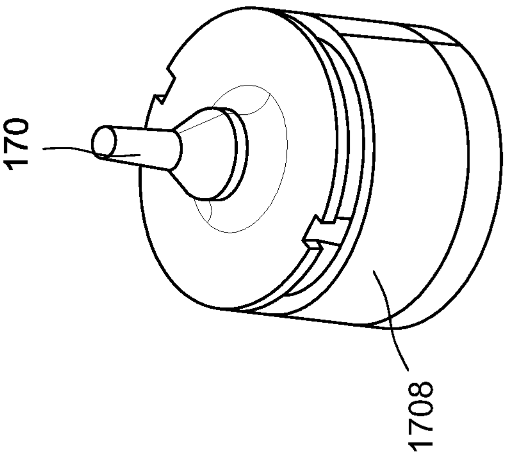


FIG. 66A

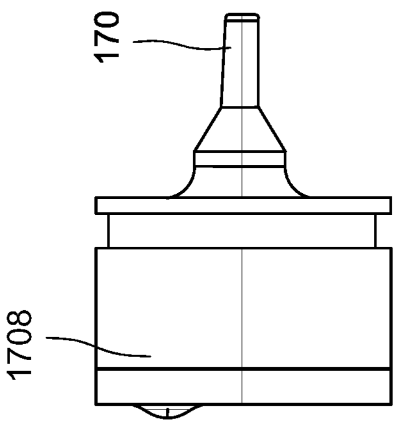


FIG. 66C

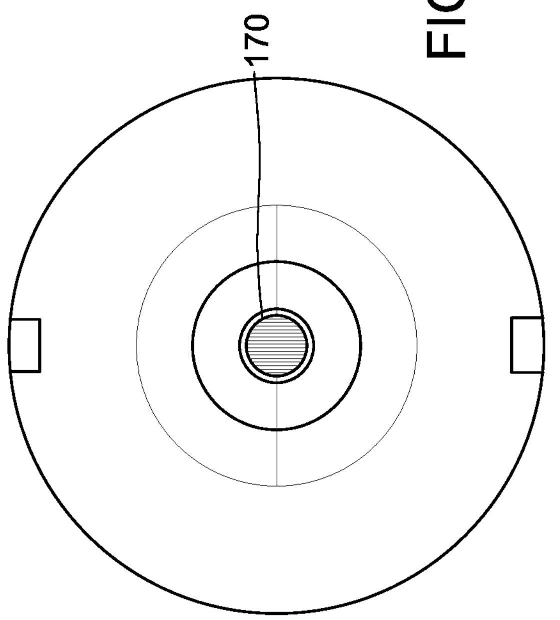


FIG. 66B

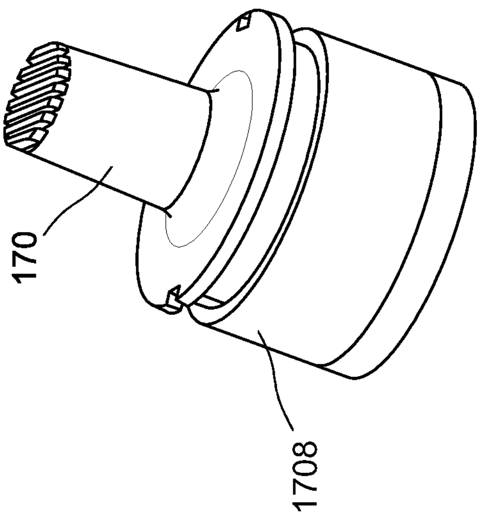


FIG. 67A

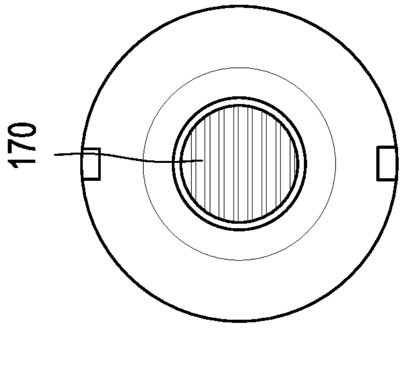


FIG. 67B

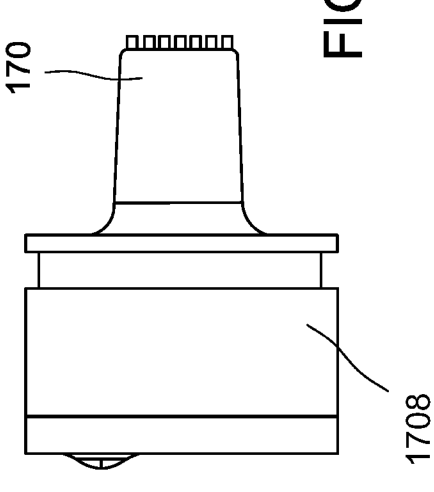


FIG. 67C

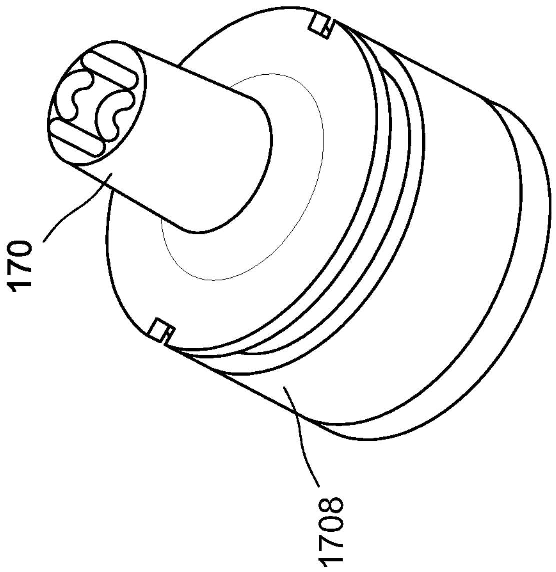


FIG. 68A

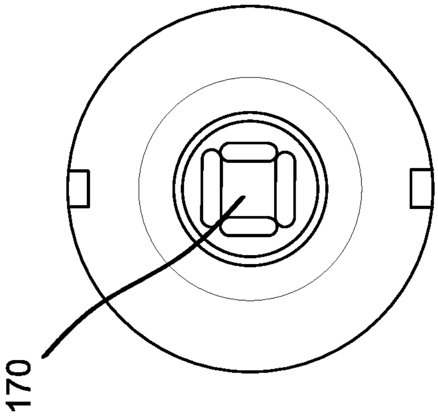


FIG. 68B

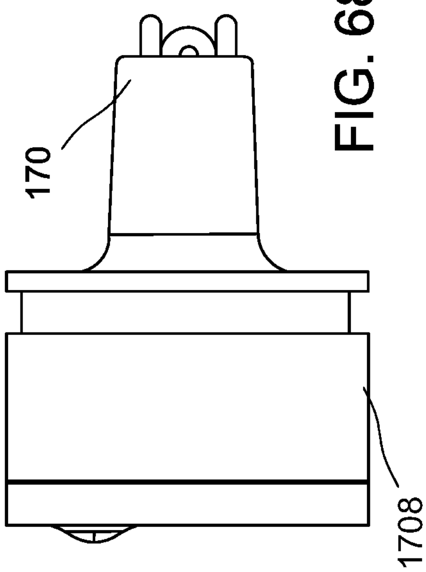


FIG. 68C

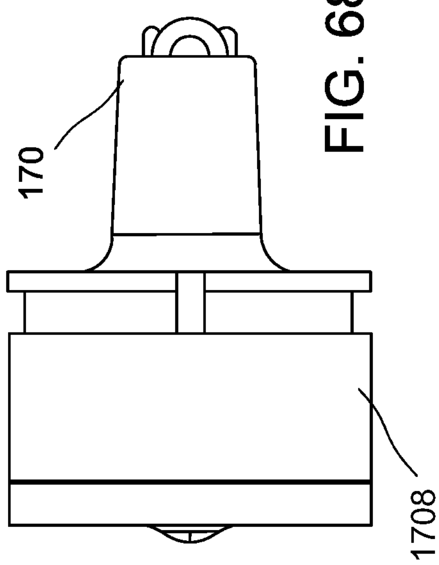


FIG. 68D

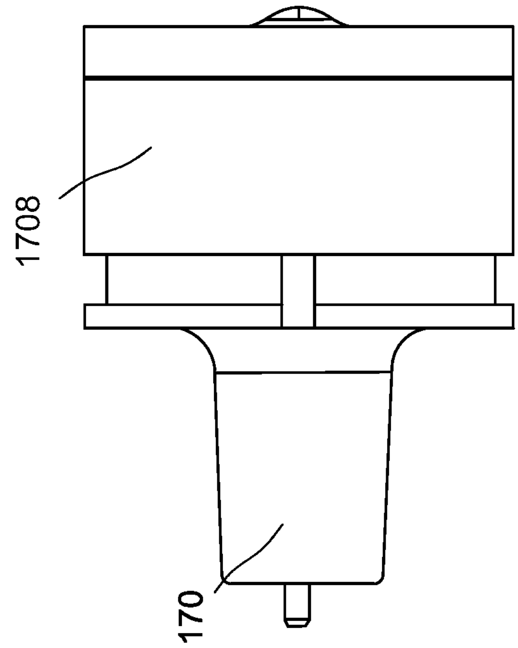


FIG. 69B

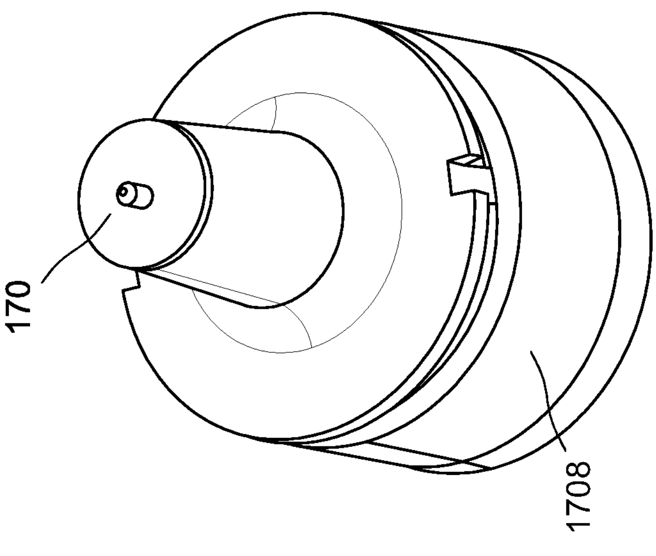


FIG. 69A

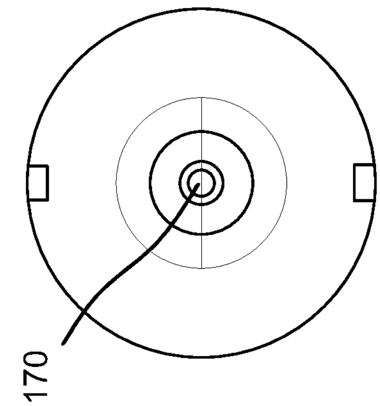


FIG. 70B

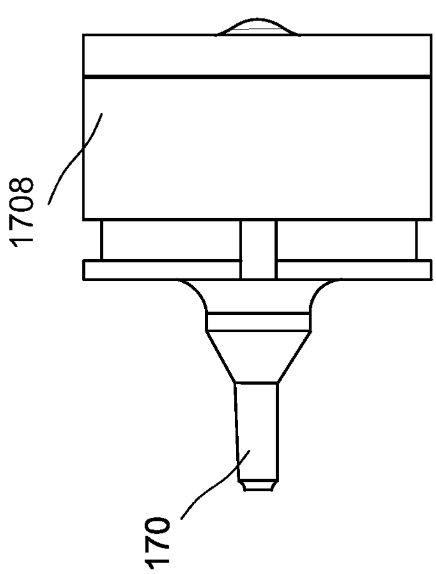


FIG. 70C

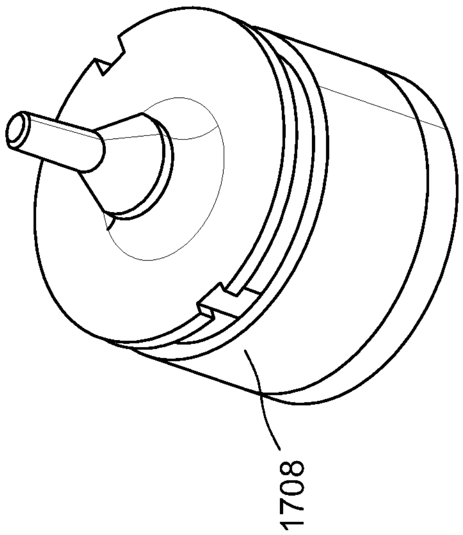


FIG. 70A

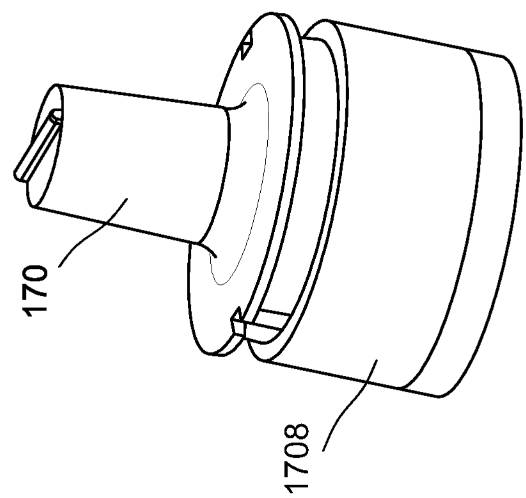


FIG. 71A

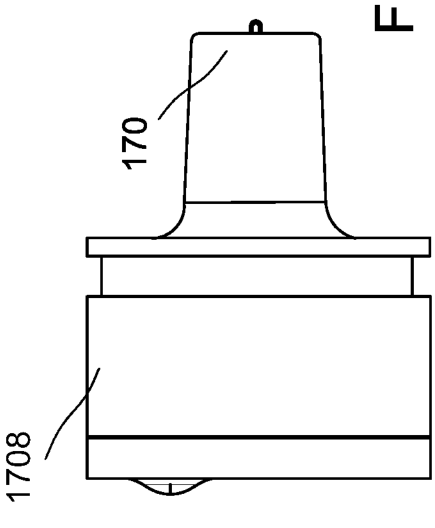


FIG. 71C

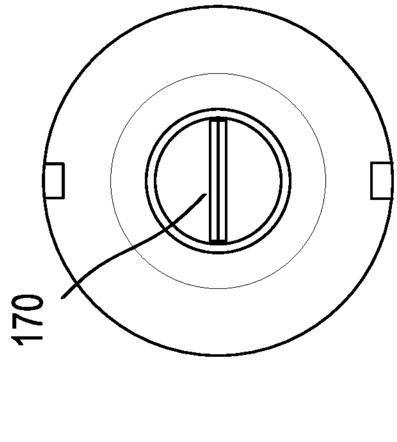


FIG. 71B

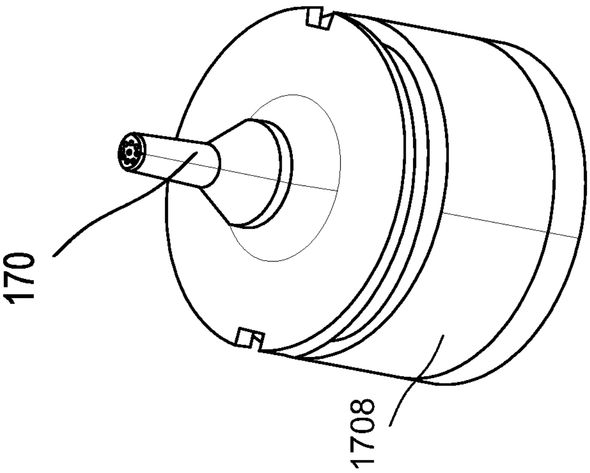


FIG. 72A

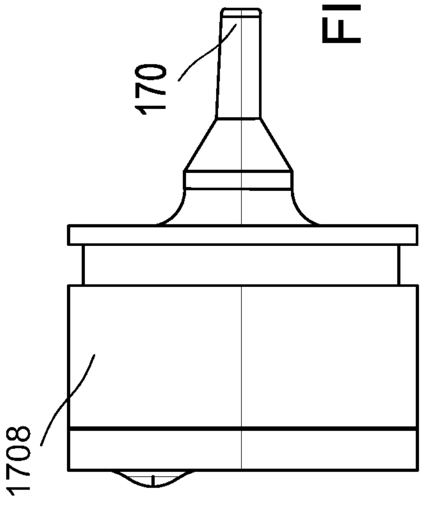


FIG. 72C

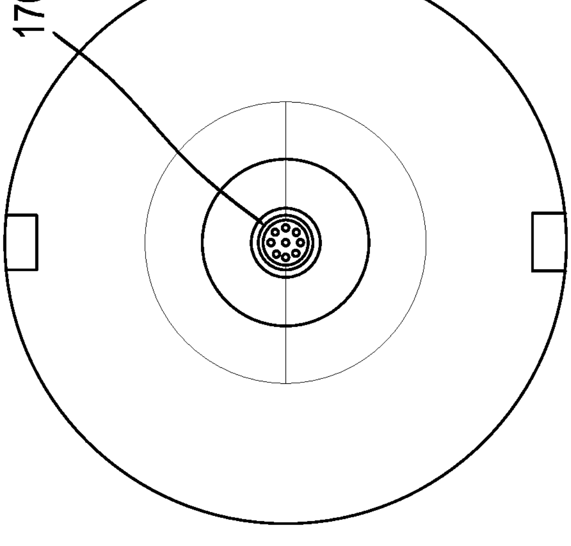


FIG. 72B

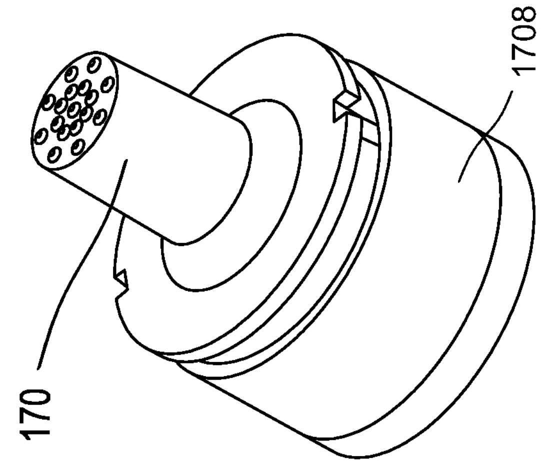


FIG. 73A

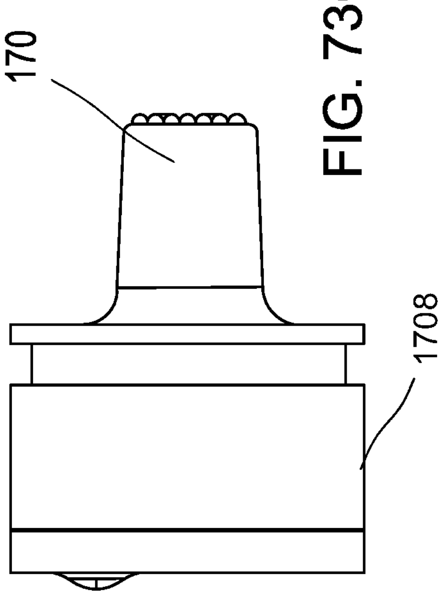


FIG. 73C

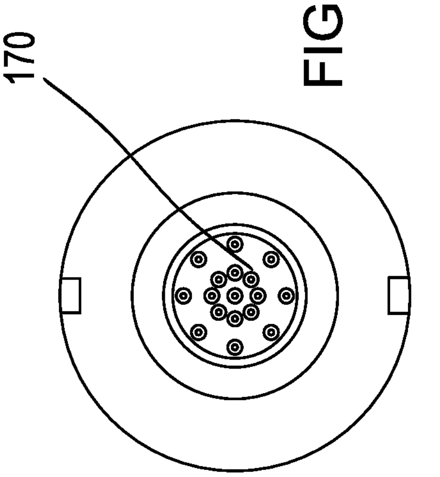


FIG. 73B

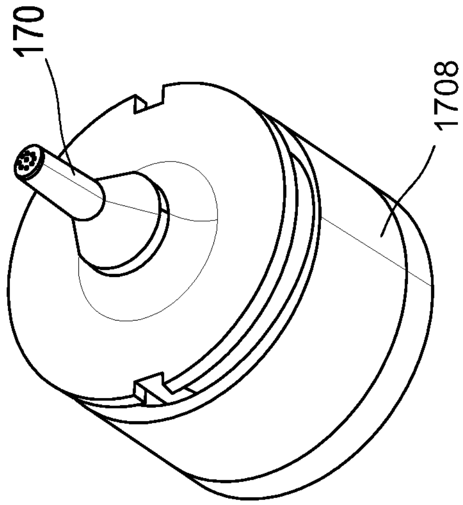


FIG. 74A

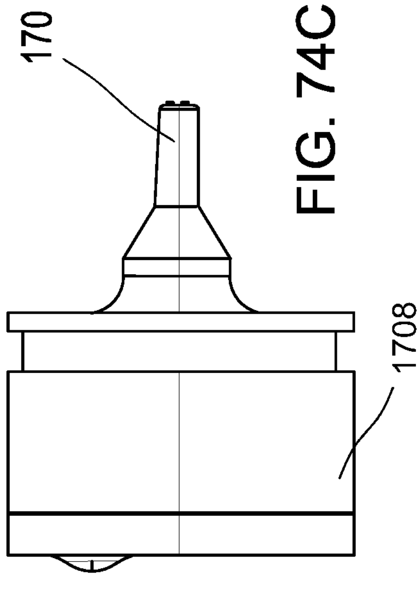


FIG. 74C

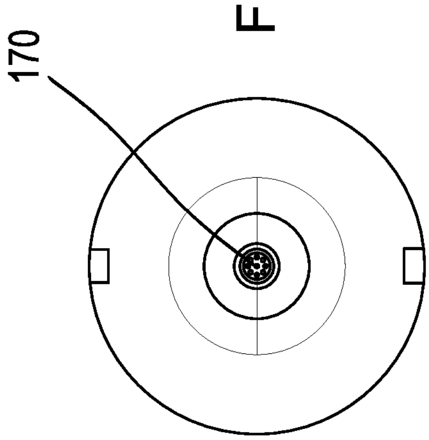


FIG. 74B

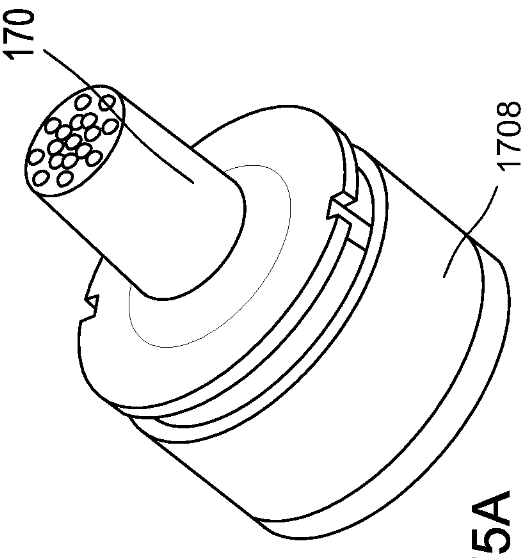


FIG. 75A

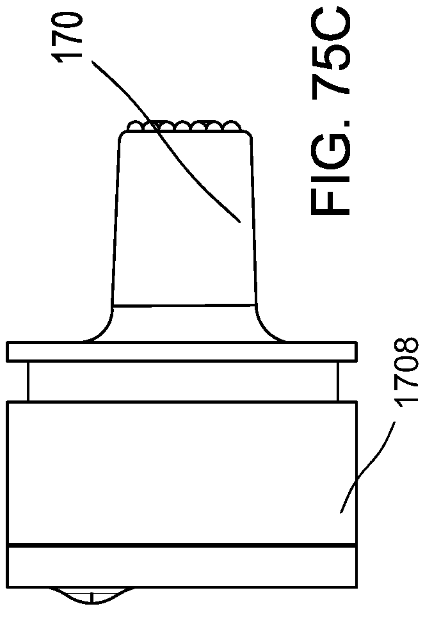


FIG. 75C

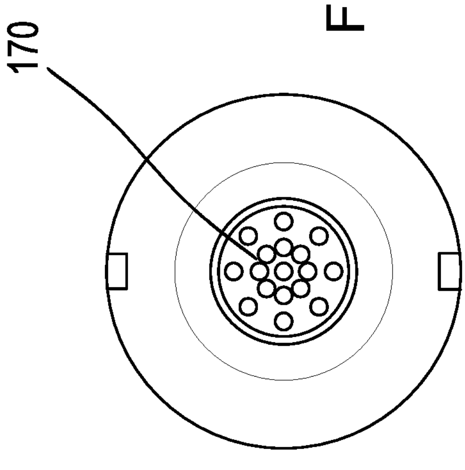


FIG. 75B

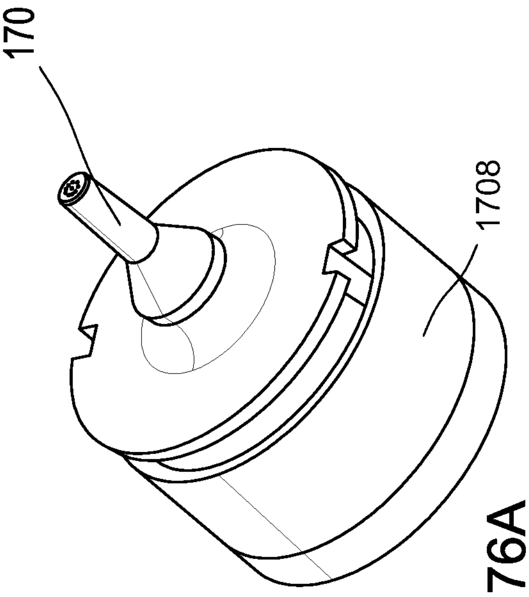


FIG. 76A

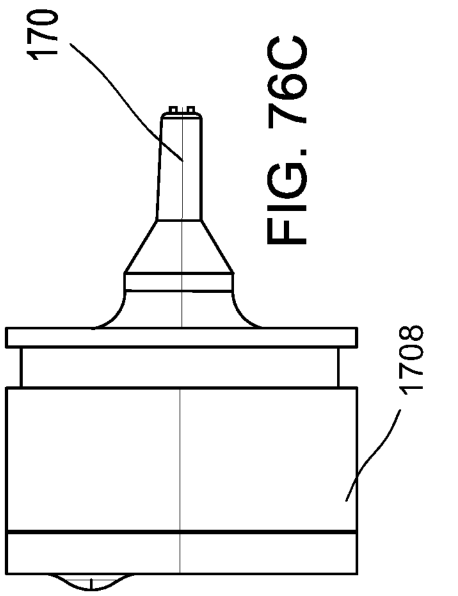


FIG. 76C

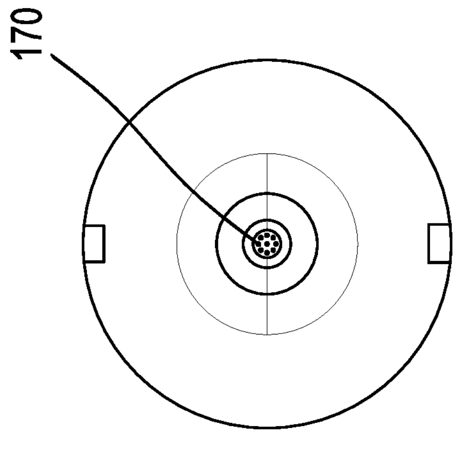


FIG. 76B

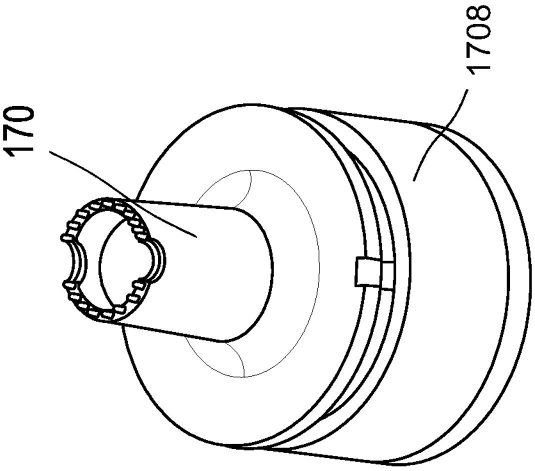


FIG. 77A

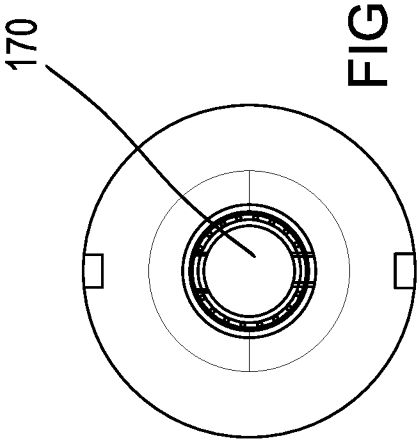


FIG. 77B

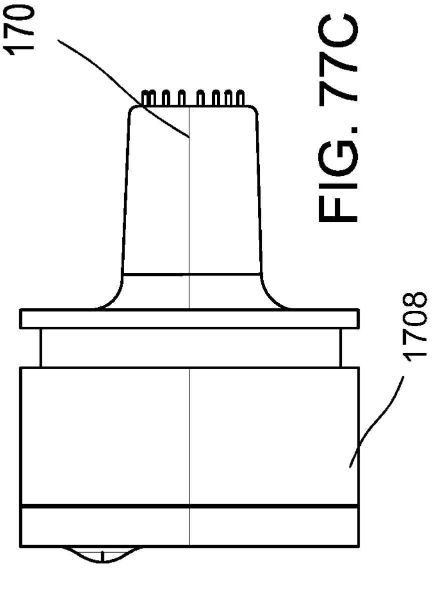


FIG. 77C

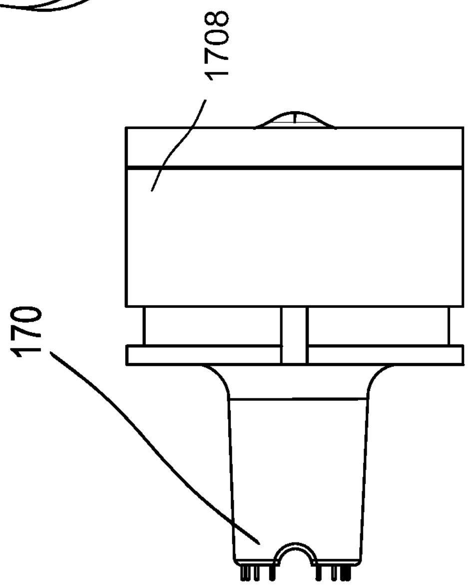


FIG. 77D

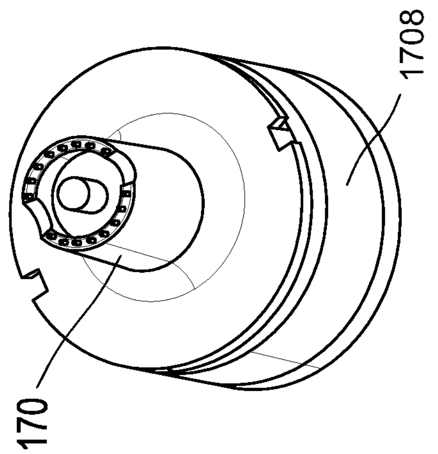


FIG. 78A

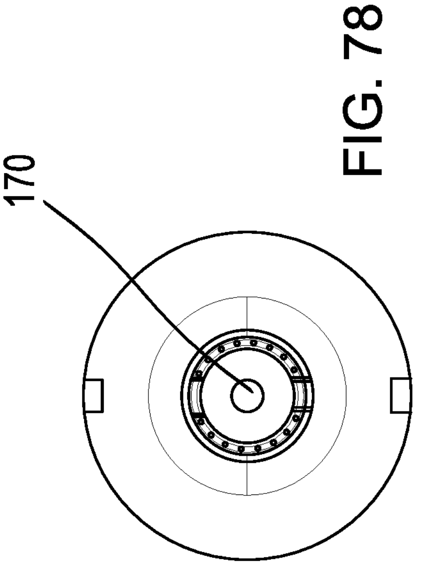


FIG. 78B

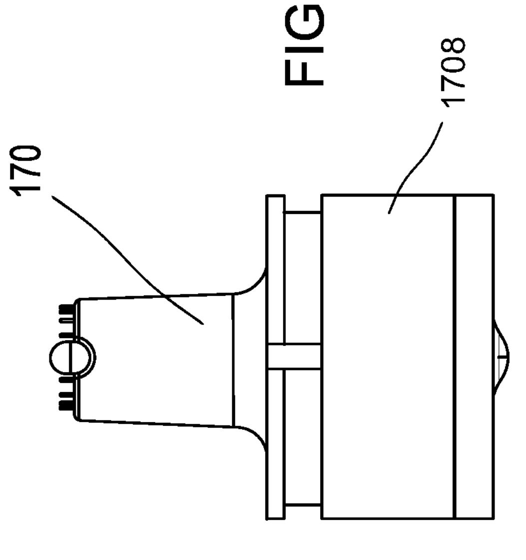


FIG. 78C

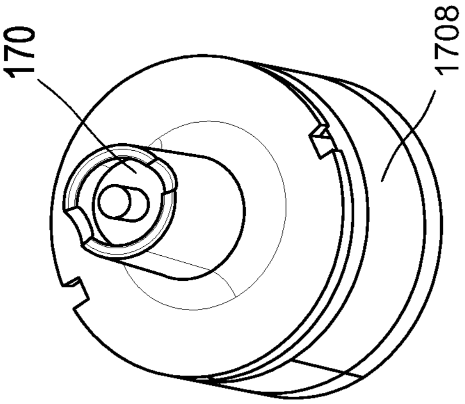


FIG. 79A

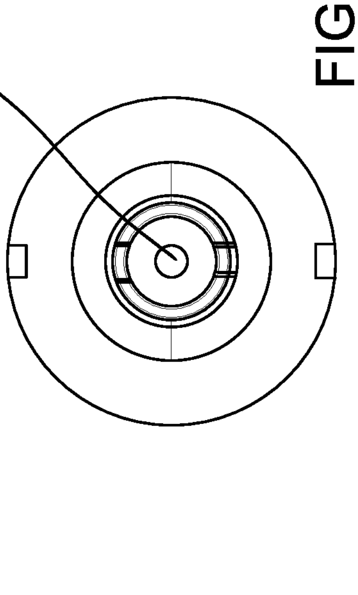


FIG. 79B

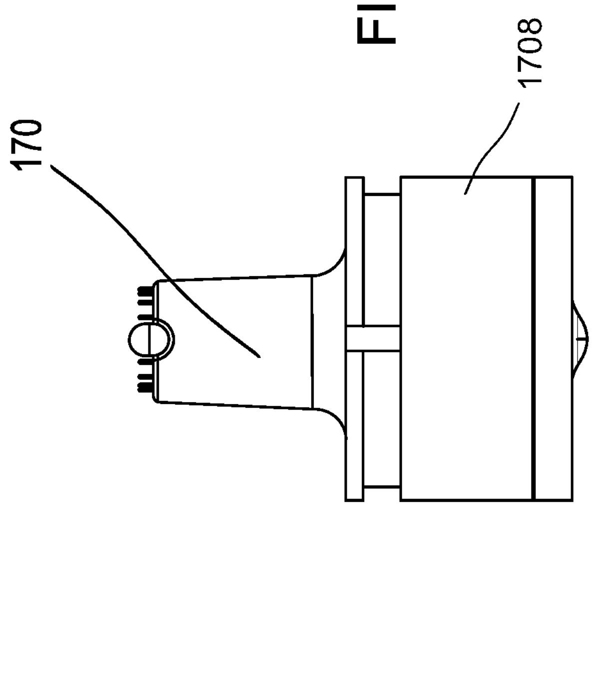


FIG. 79C

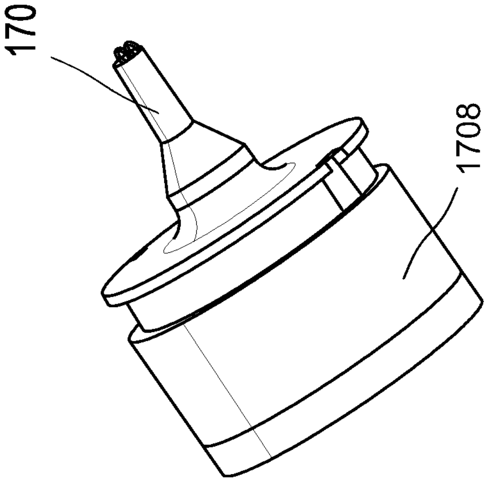


FIG. 80A

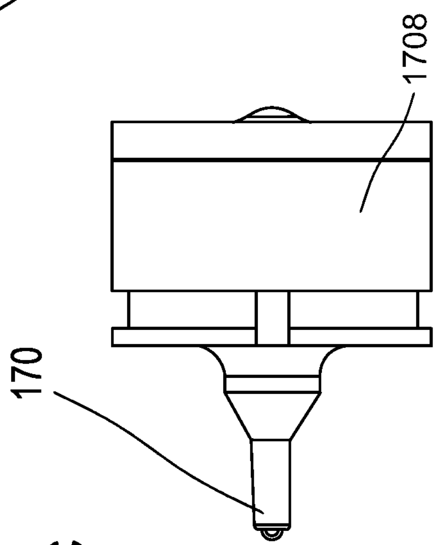


FIG. 80D

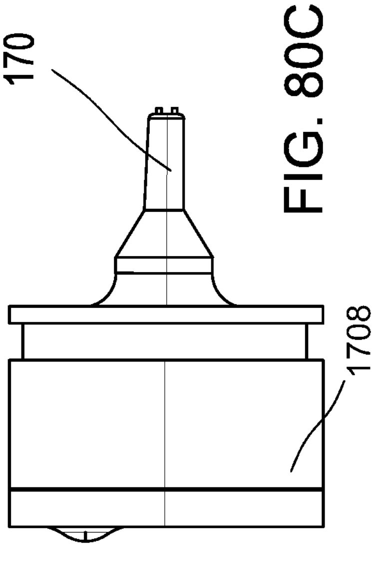


FIG. 80C

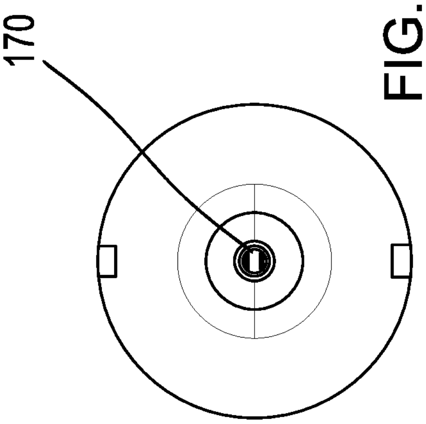


FIG. 80B

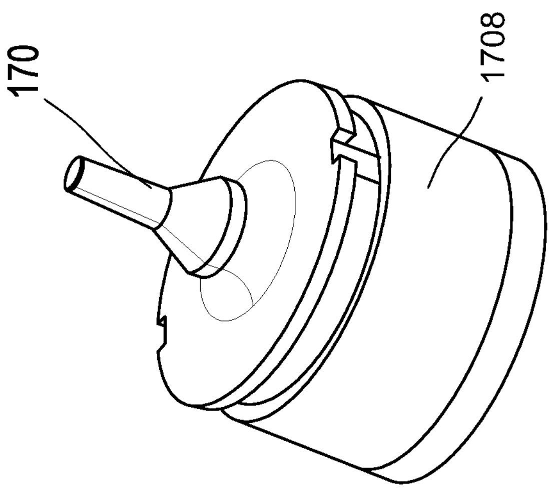


FIG. 81A

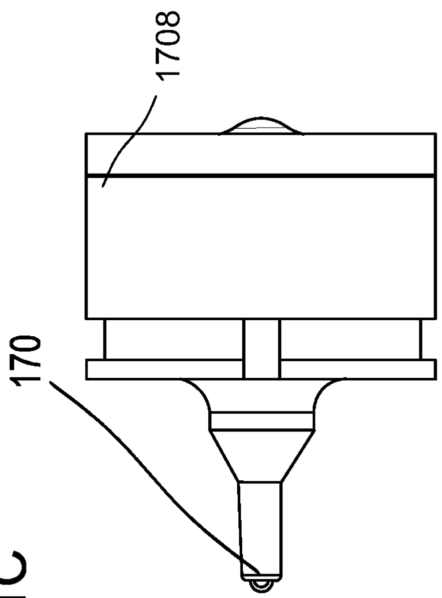


FIG. 81D

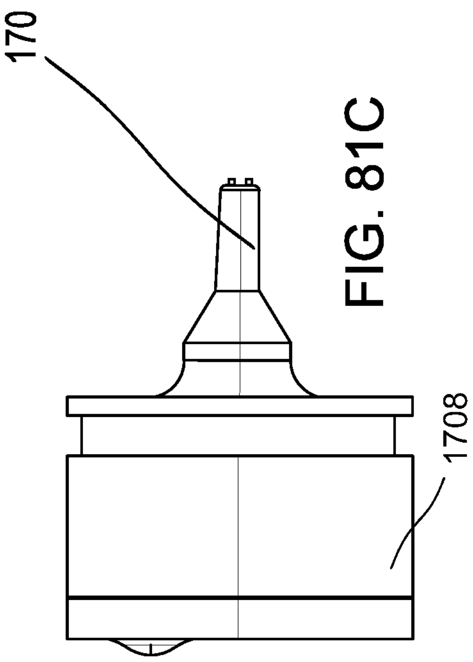


FIG. 81C

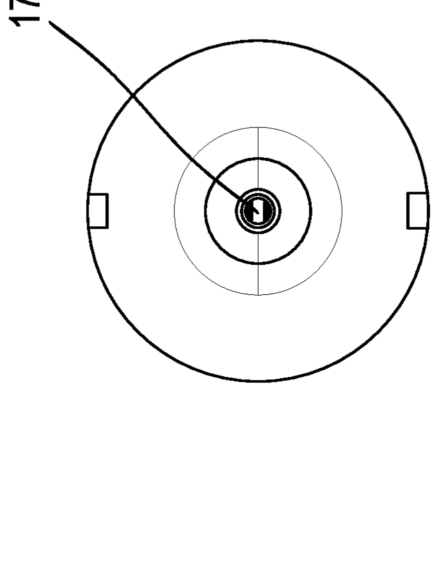


FIG. 81B

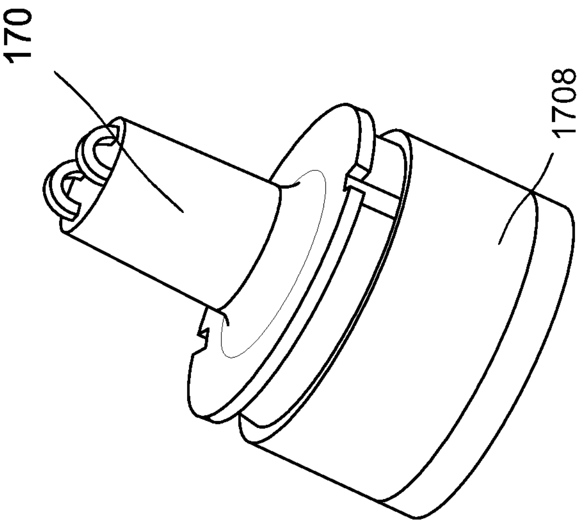


FIG. 82A

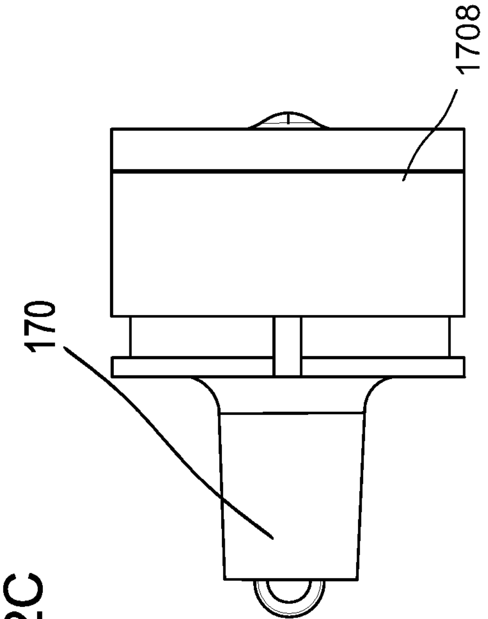


FIG. 82D

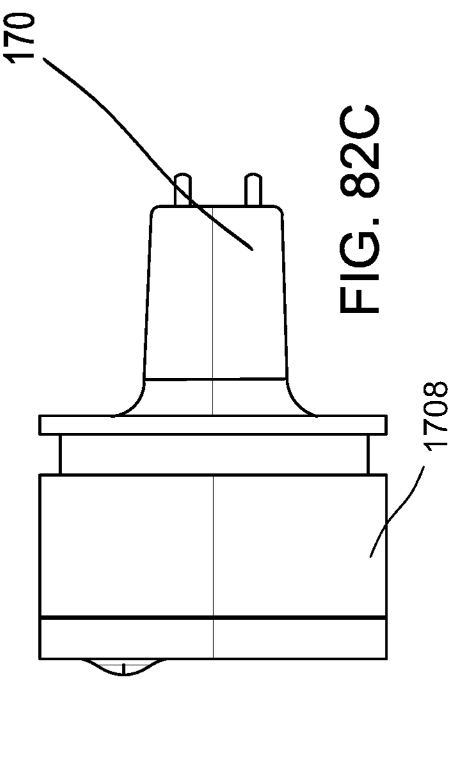


FIG. 82C

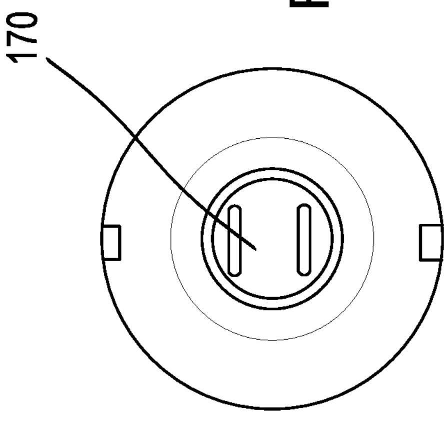


FIG. 82B

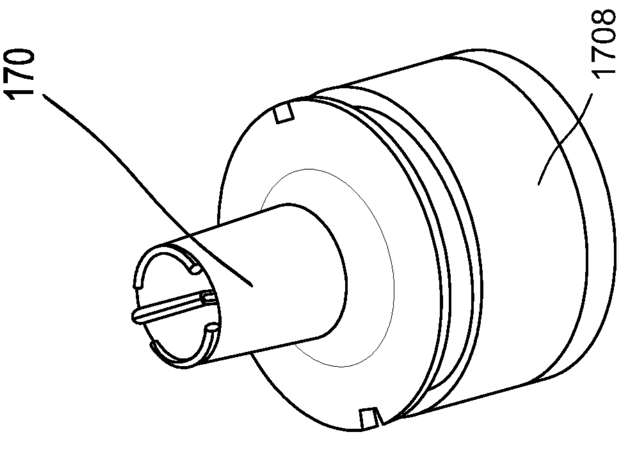


FIG. 83A

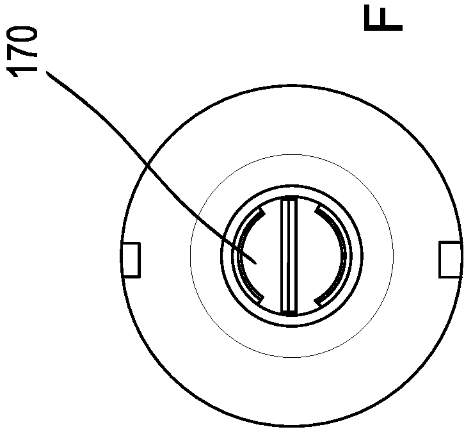


FIG. 83B

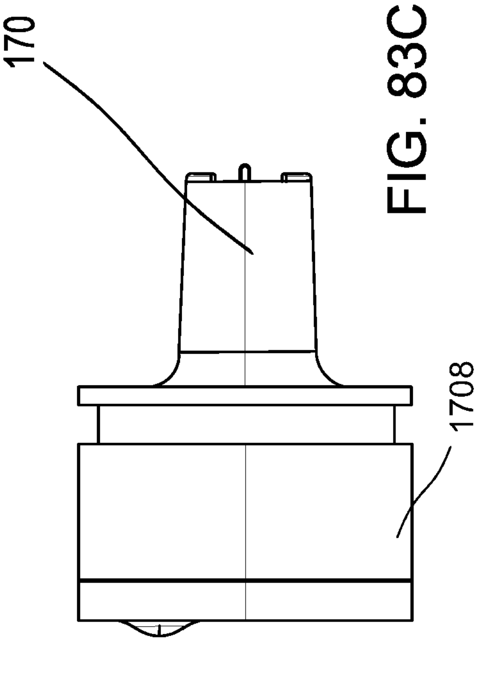


FIG. 83C

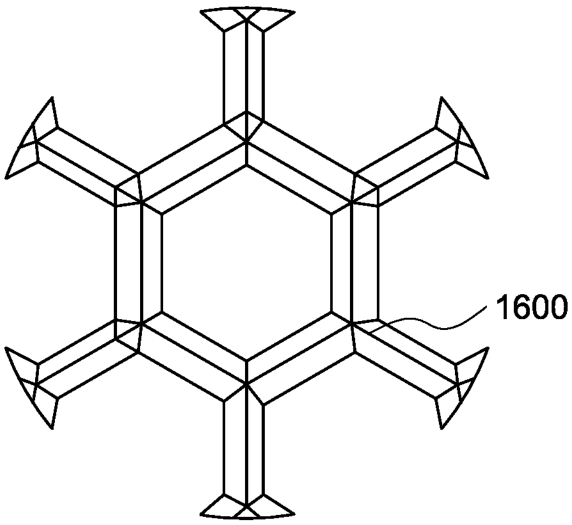


FIG. 84A

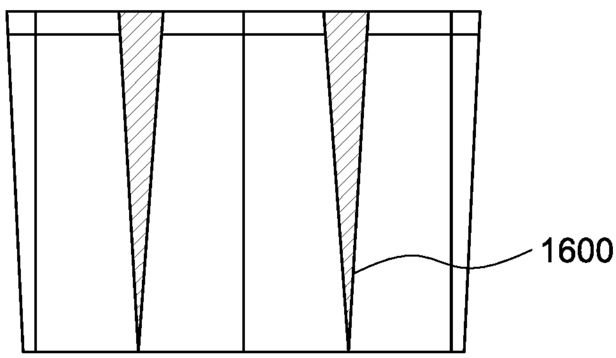


FIG. 84B

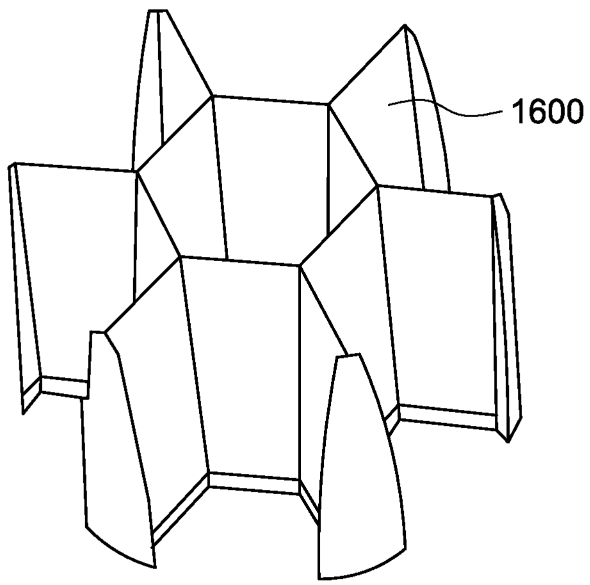


FIG. 84C

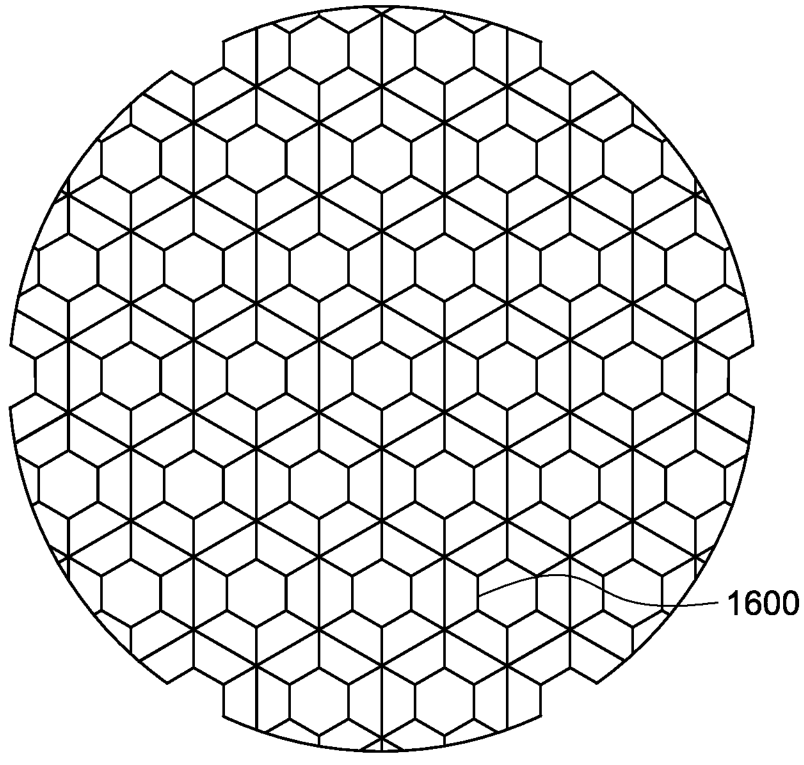


FIG. 84D

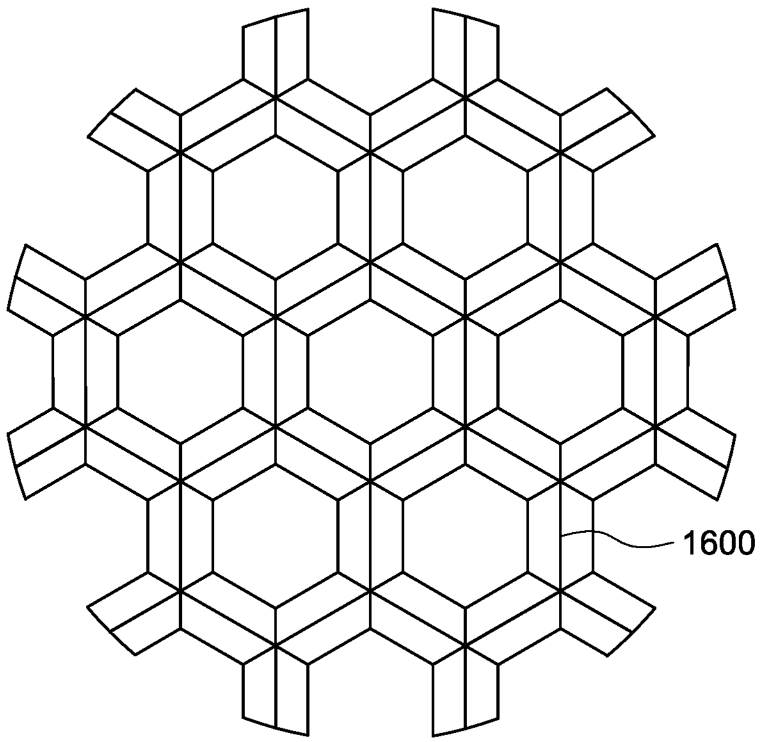


FIG. 84E

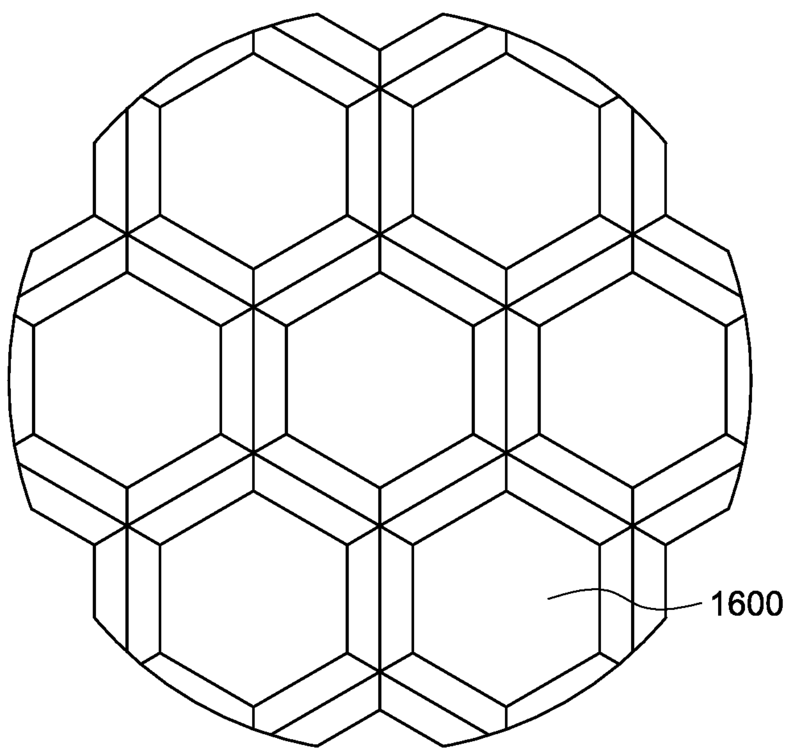


FIG. 84F

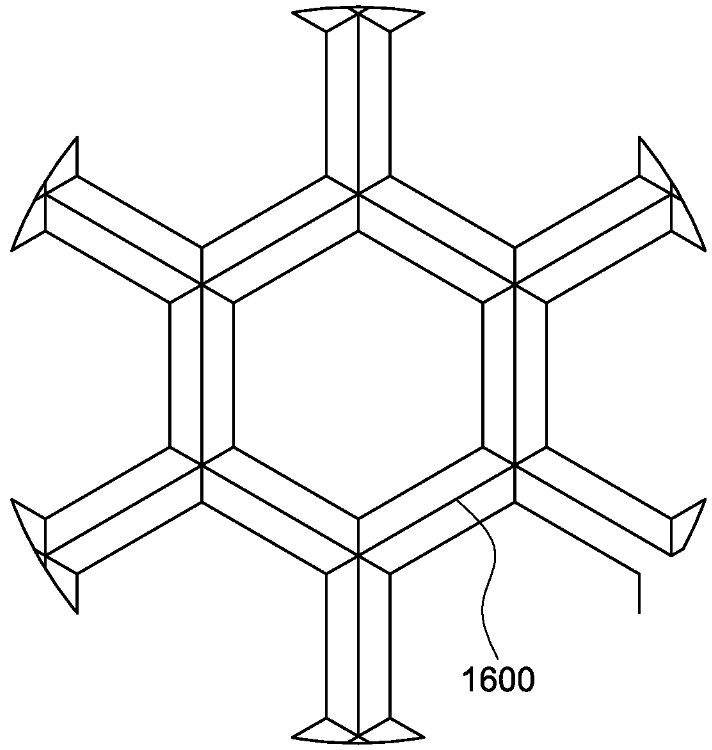


FIG. 84G

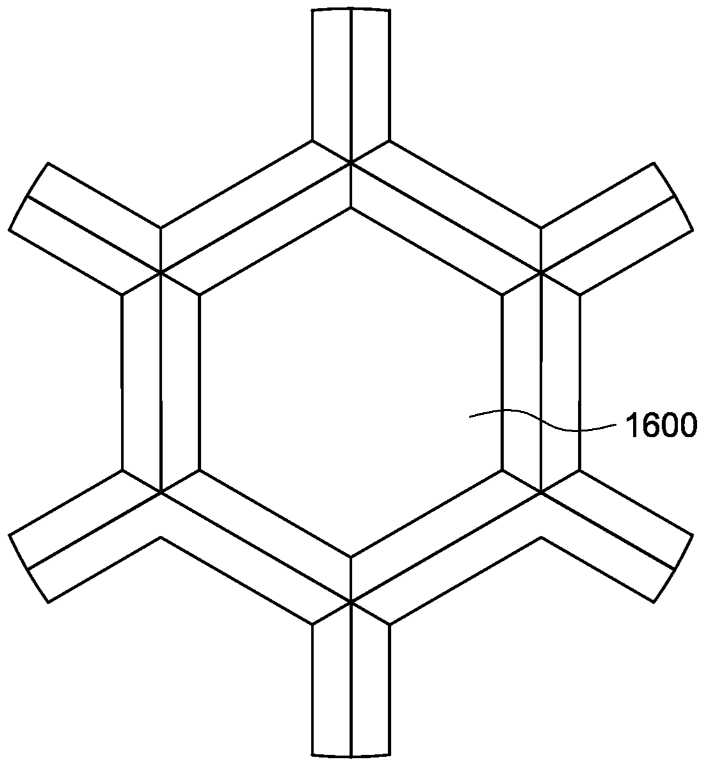


FIG. 84H

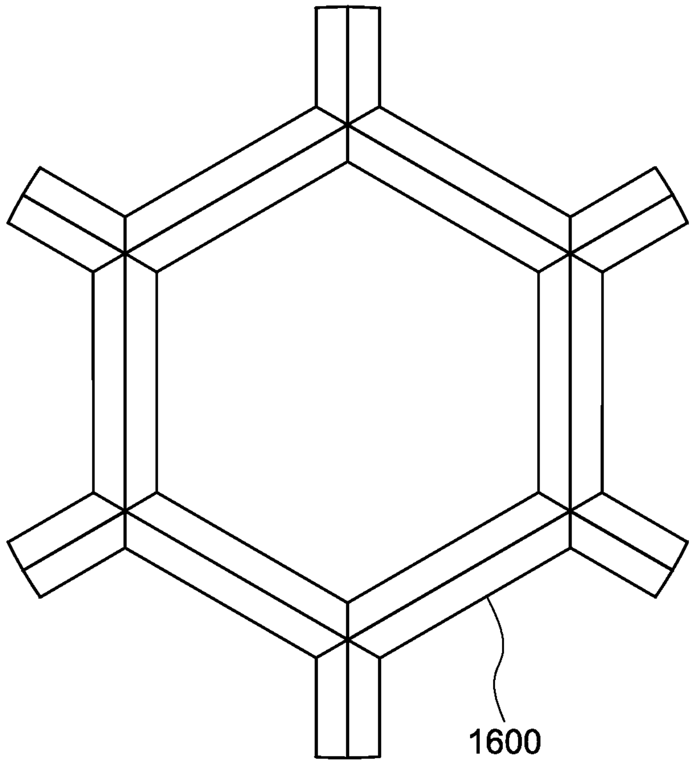


FIG. 84I

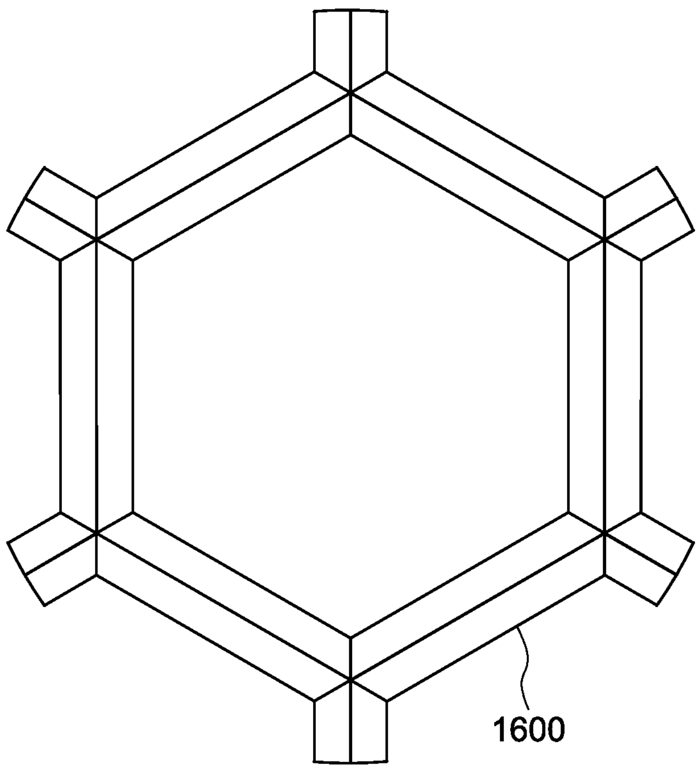


FIG. 84J

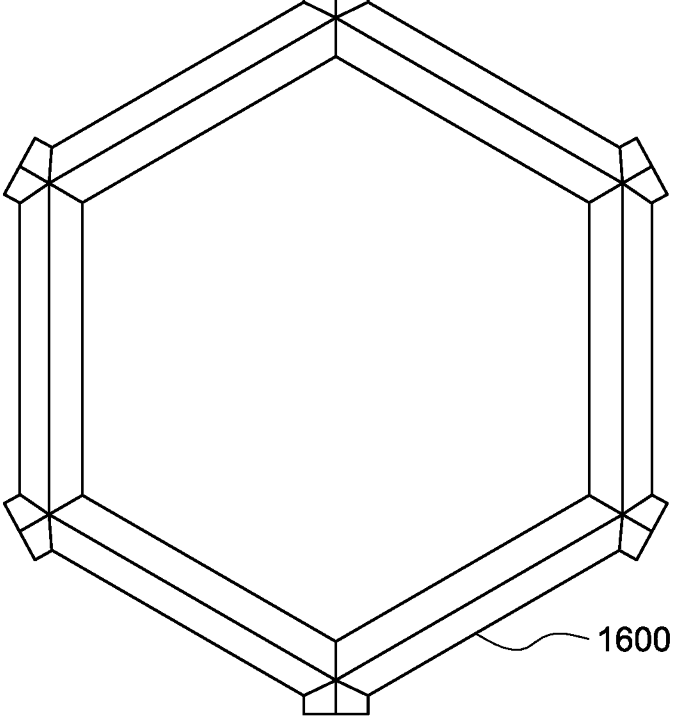


FIG. 84K

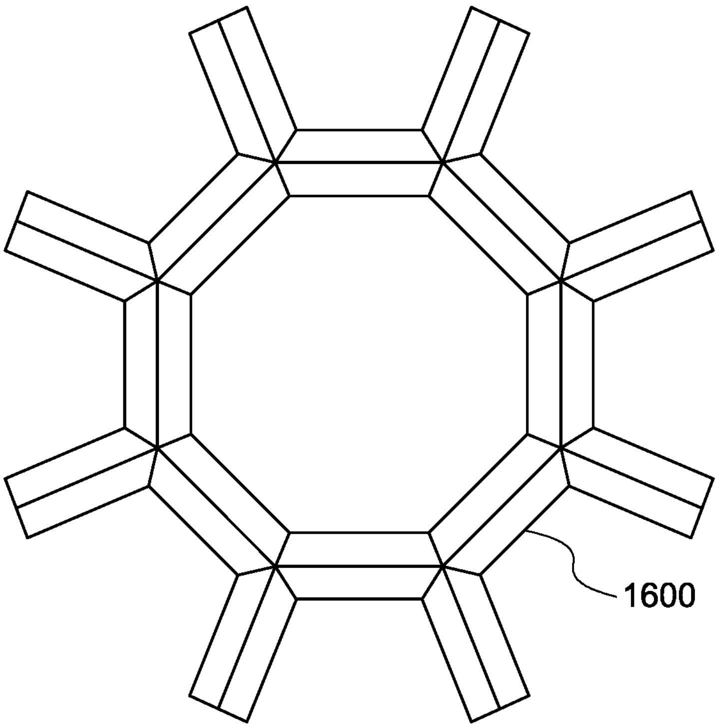


FIG. 84L

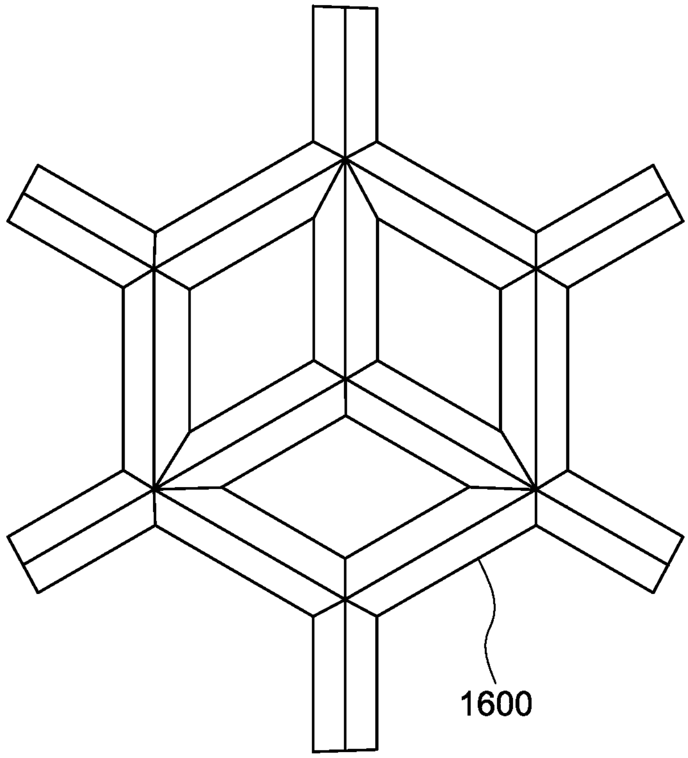


FIG. 84M

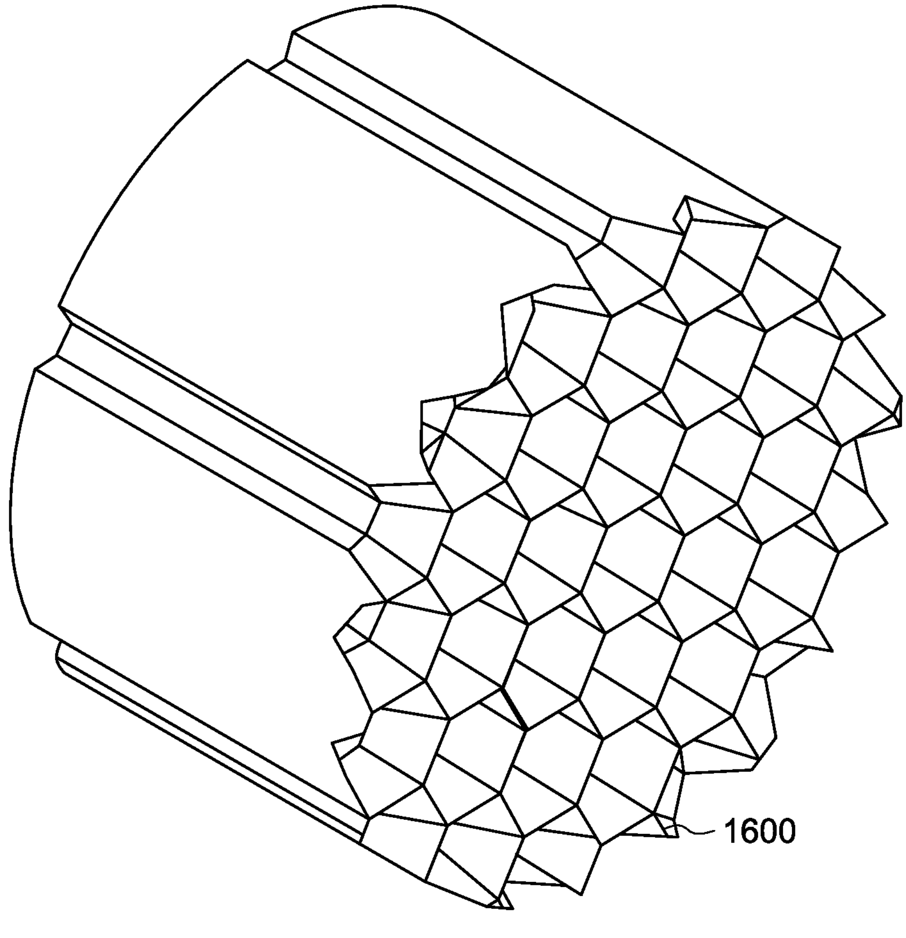


FIG. 84N

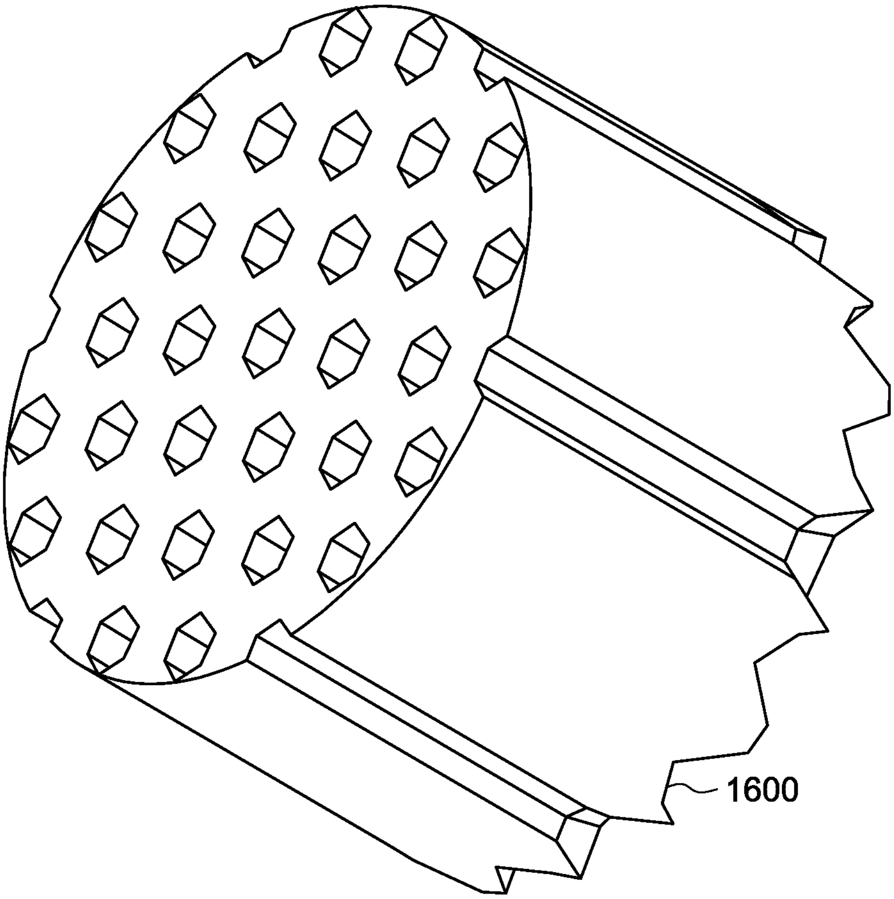


FIG. 84O

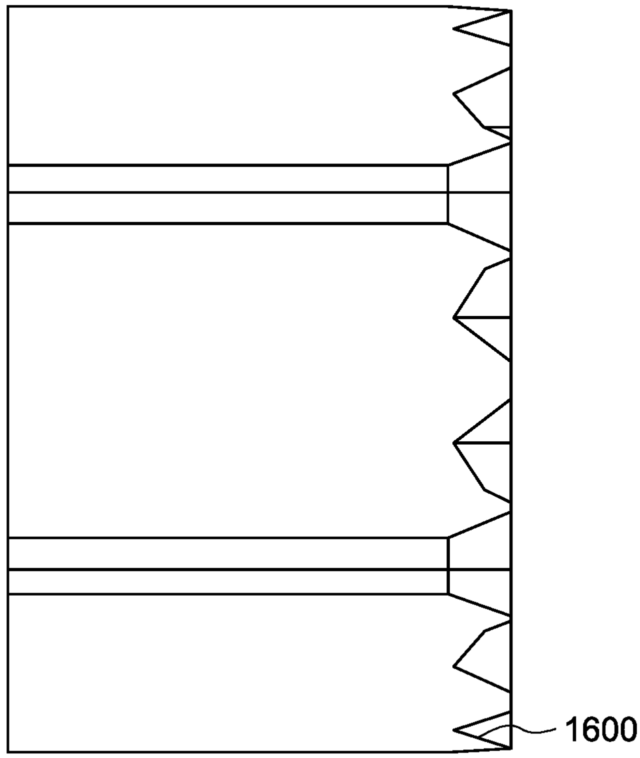


FIG. 84P

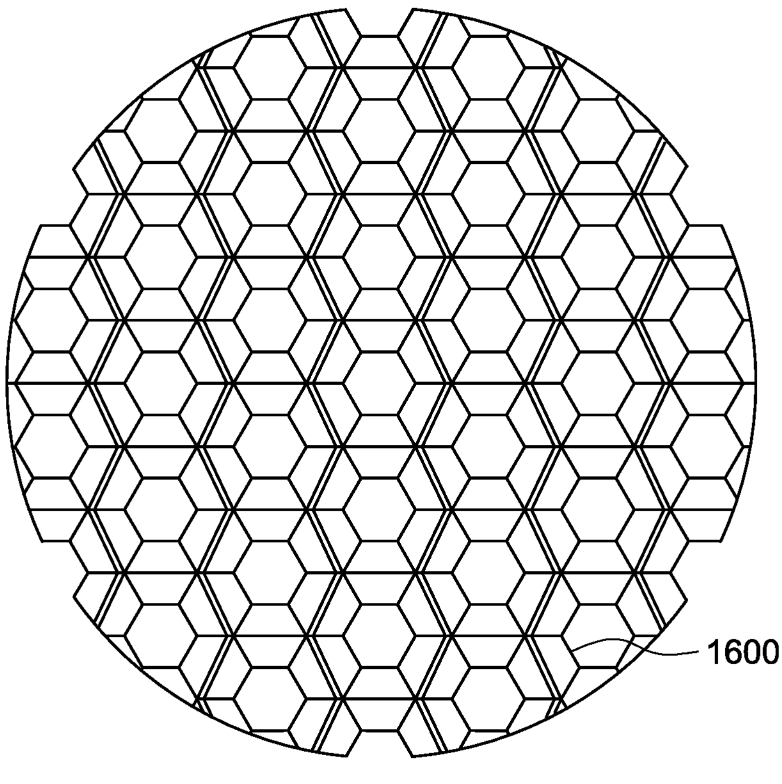


FIG. 84Q

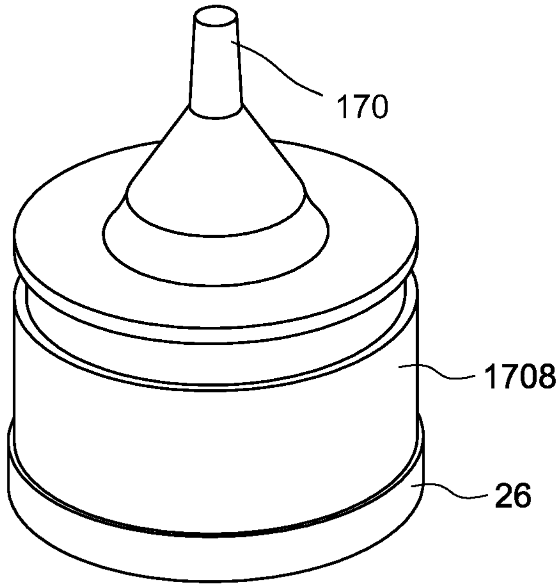


FIG. 85A

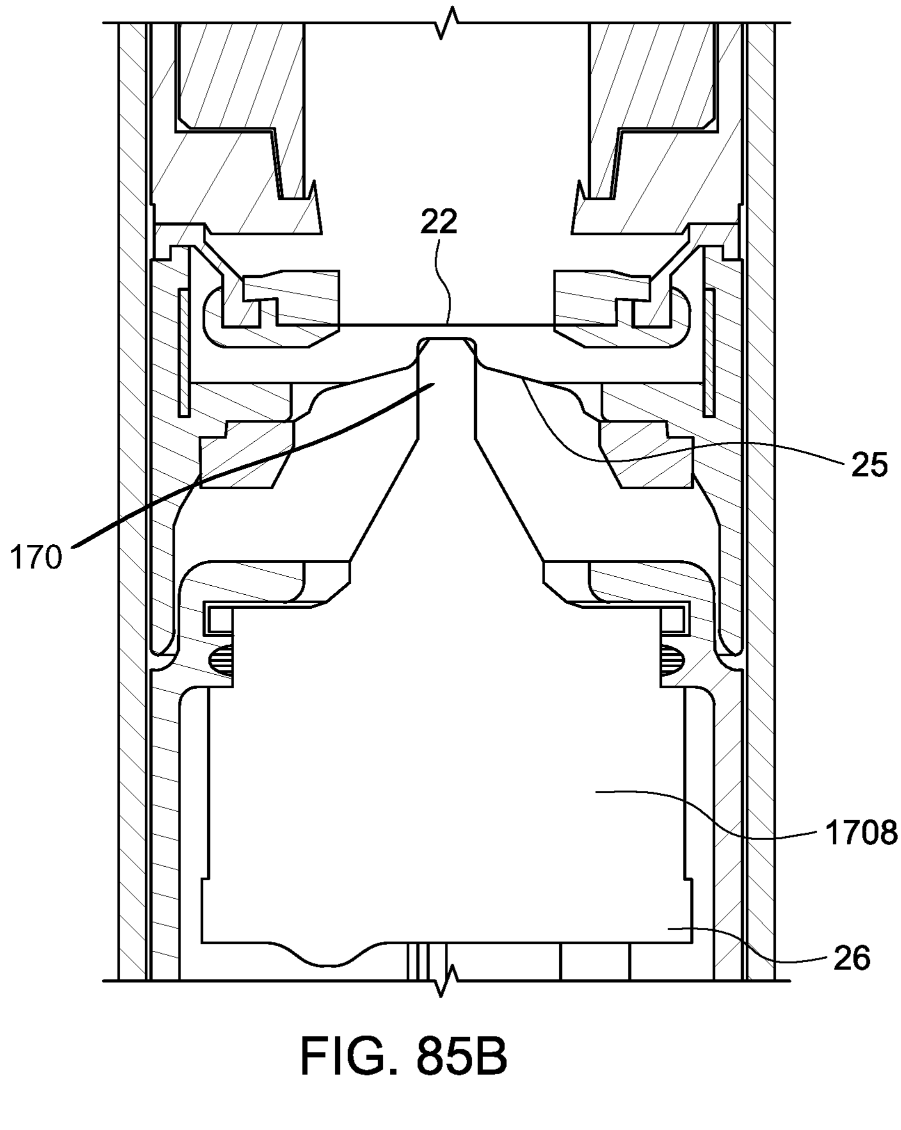


FIG. 85B

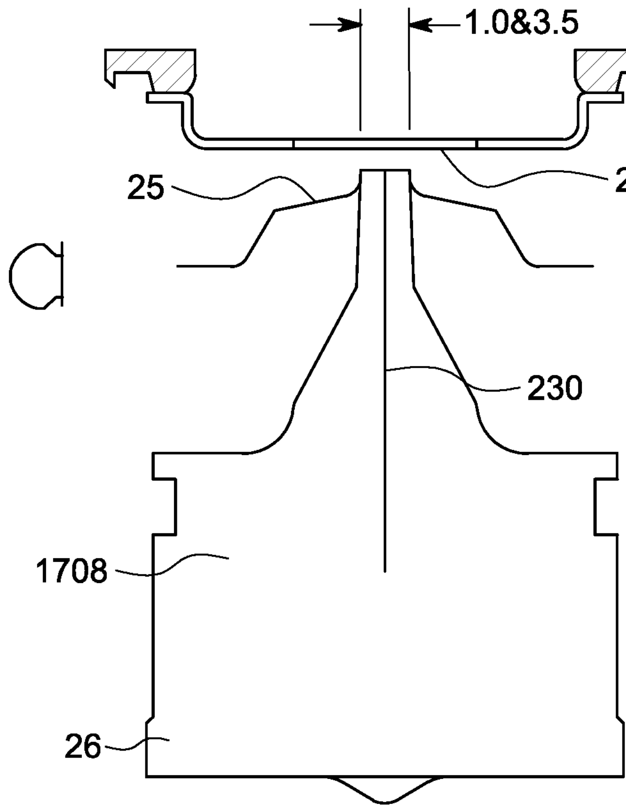


FIG. 85C

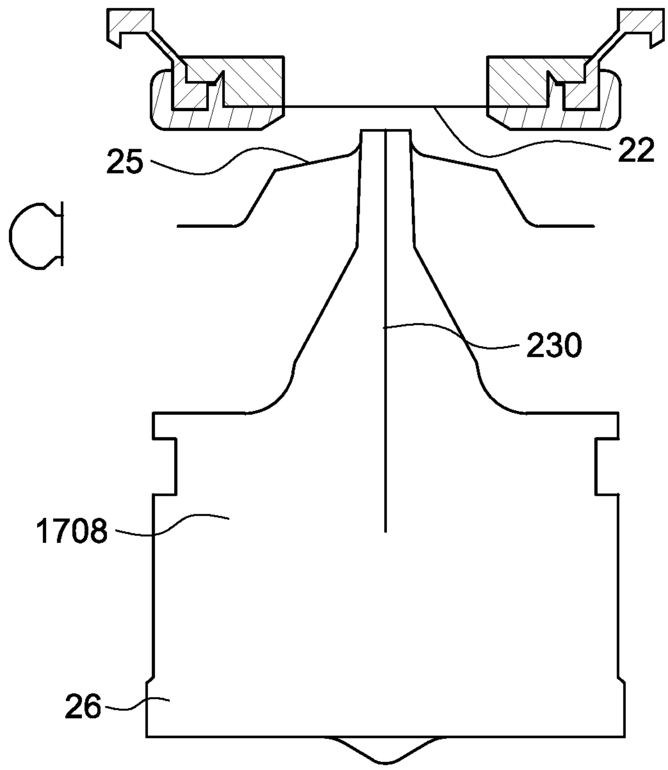


FIG. 85D

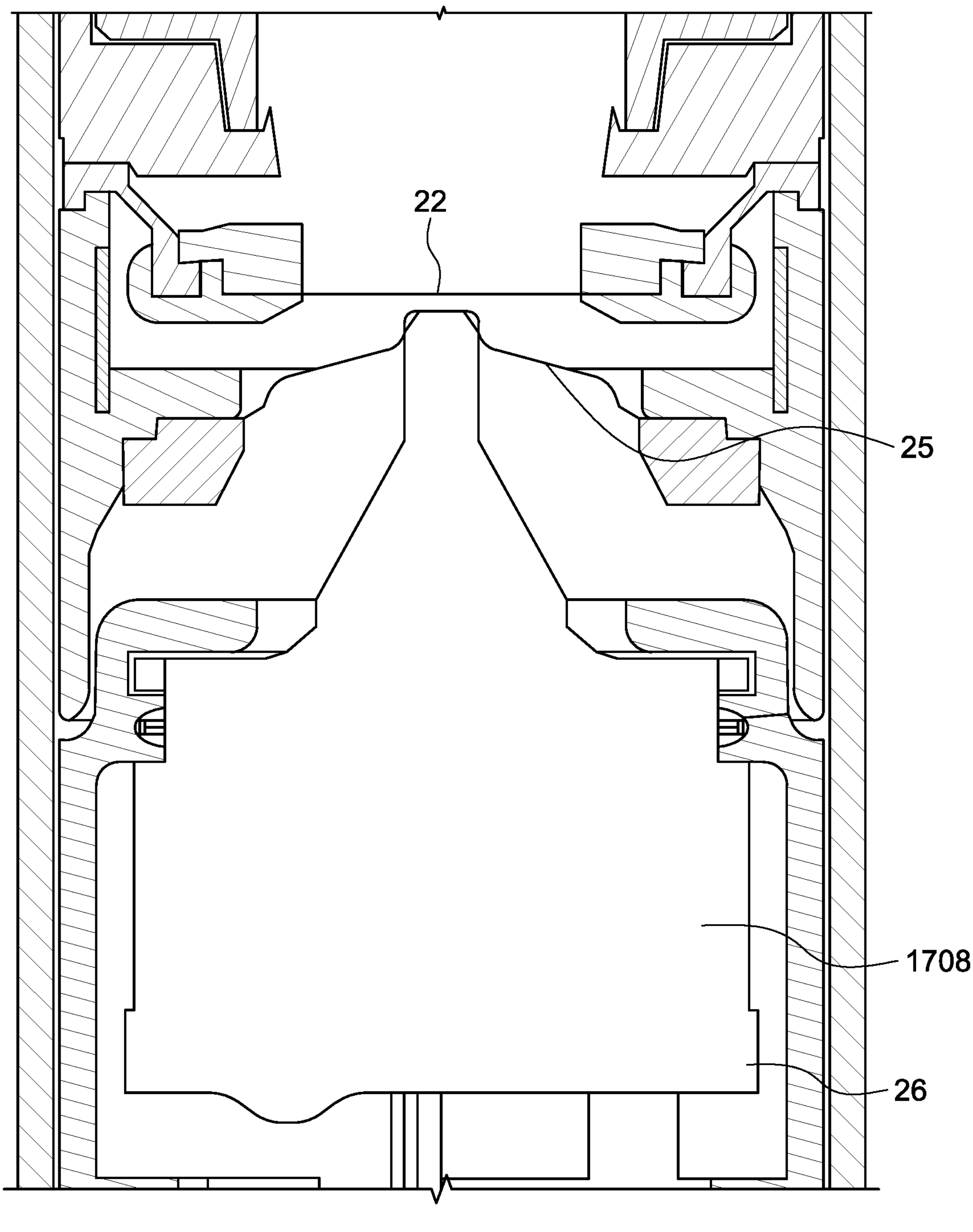


FIG. 86A

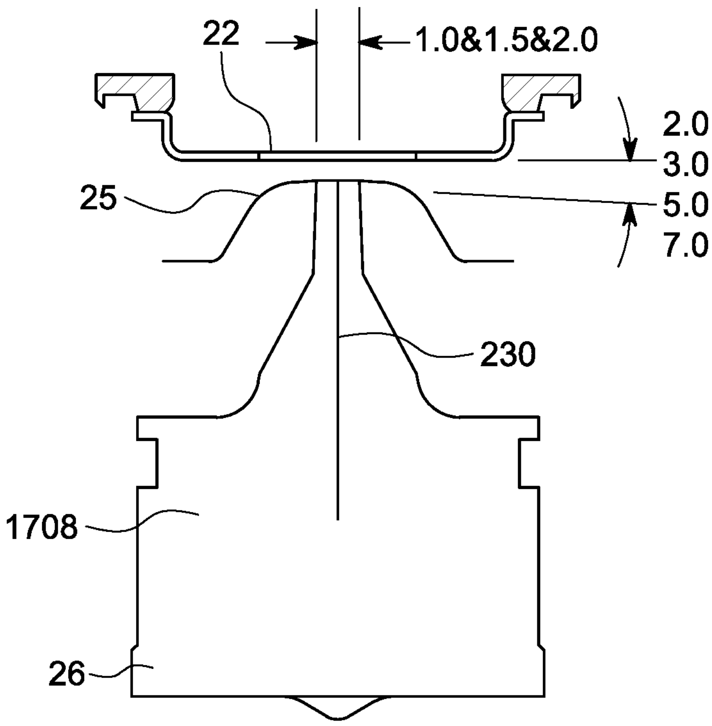


FIG. 86B

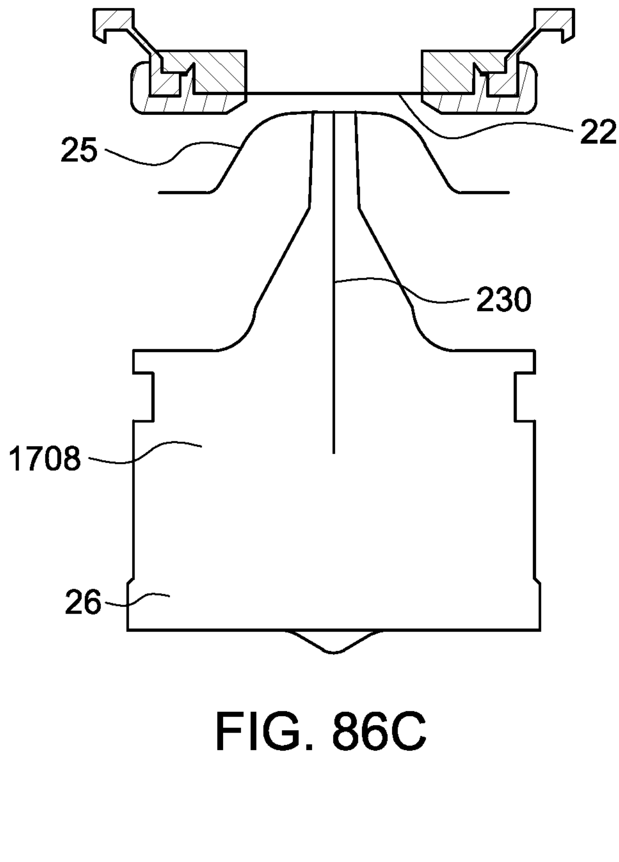


FIG. 86C

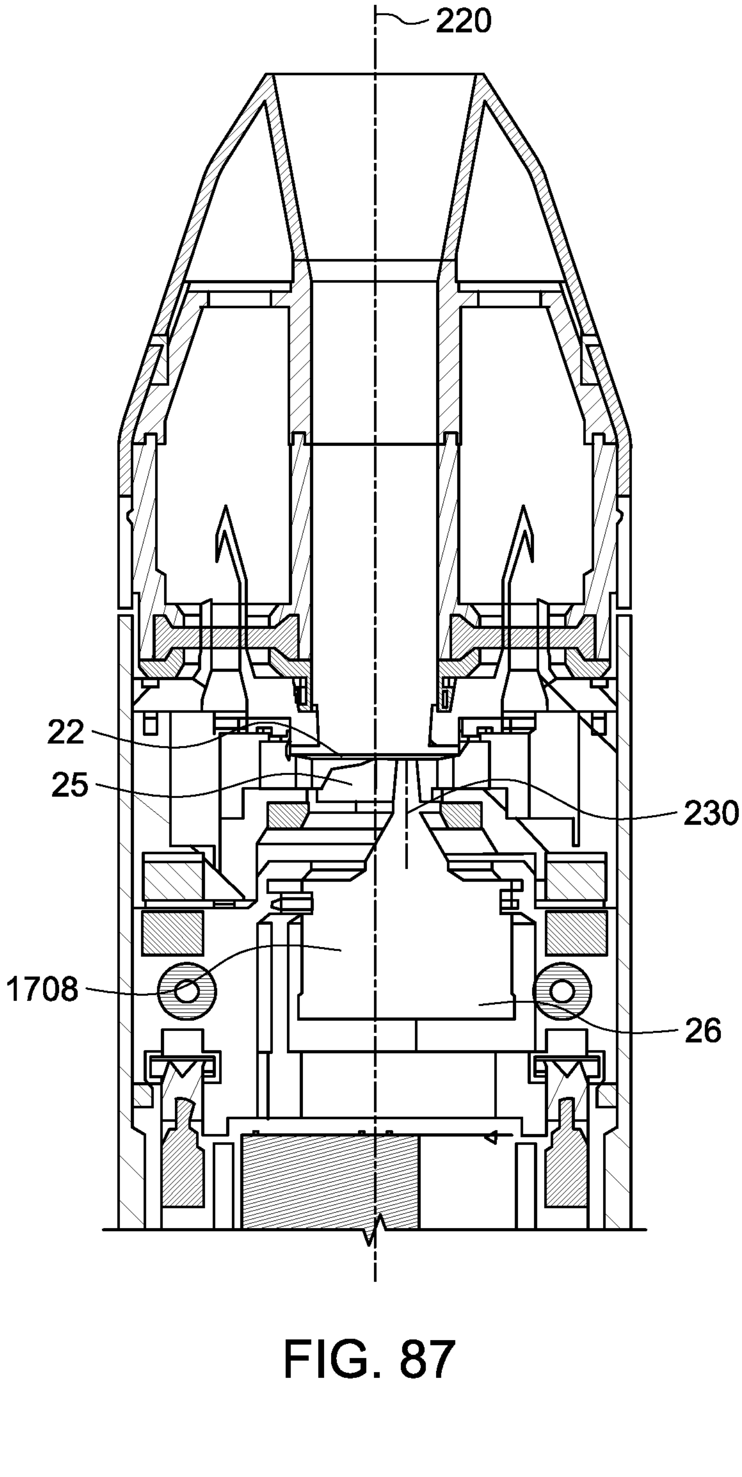


FIG. 87

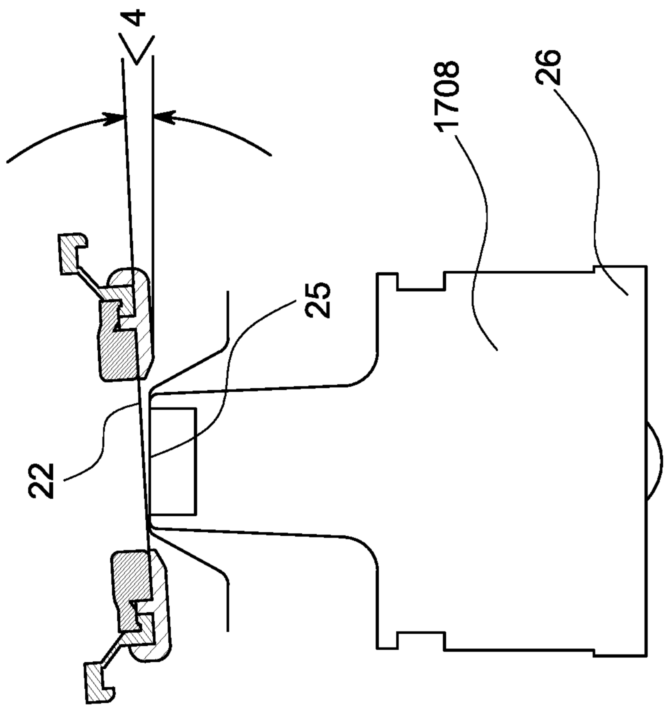


FIG. 88B

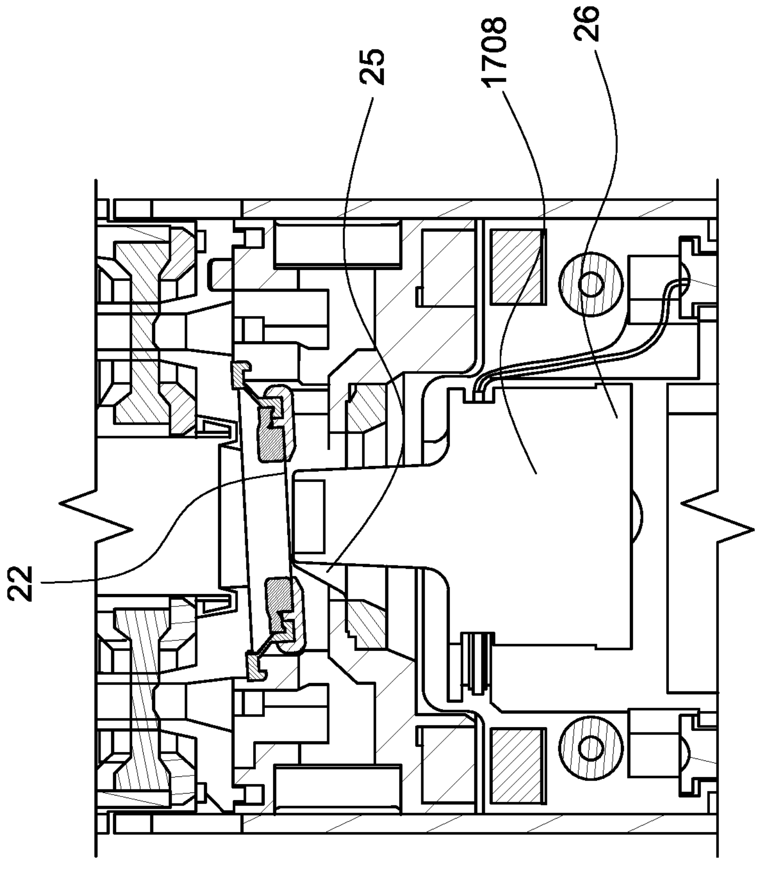


FIG. 88A

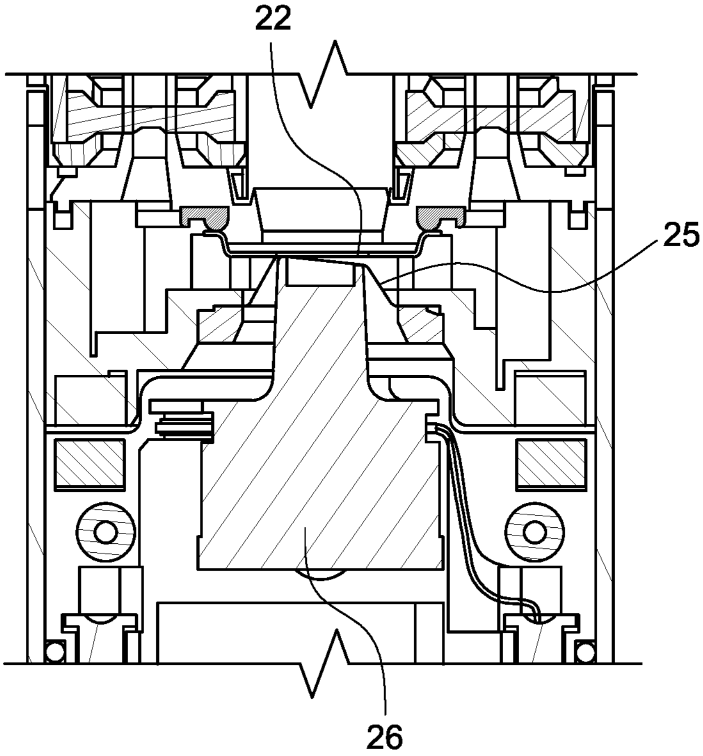


FIG. 89A

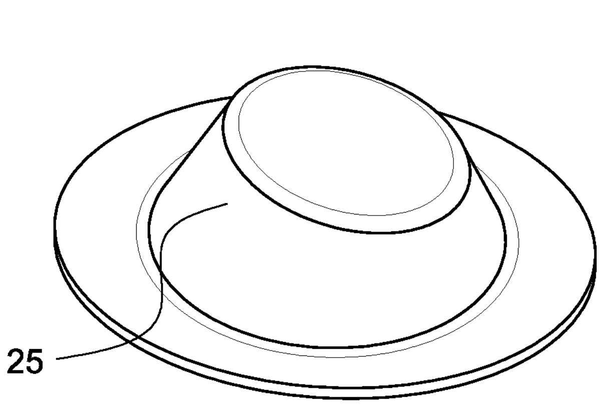


FIG. 89B

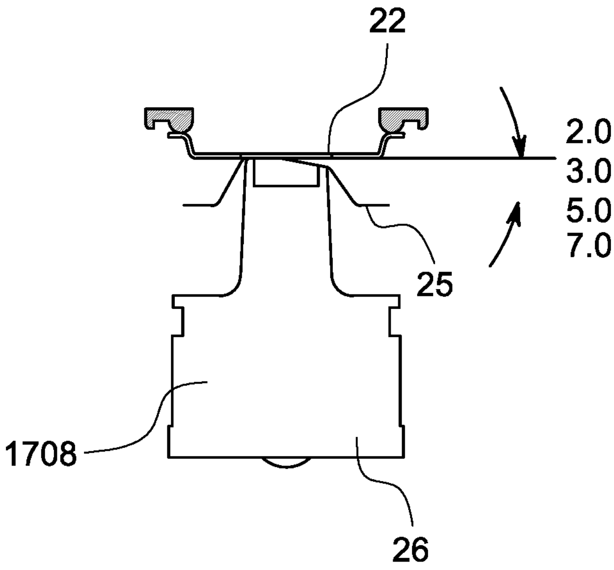


FIG. 89C

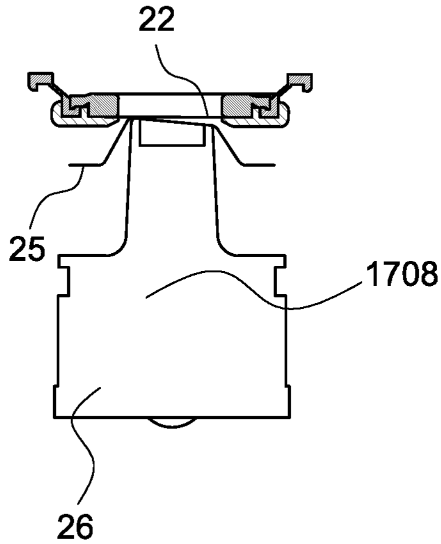


FIG. 89D

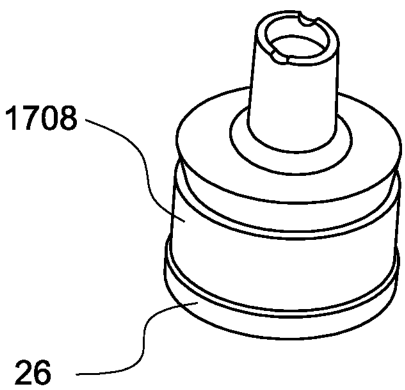


FIG. 89E

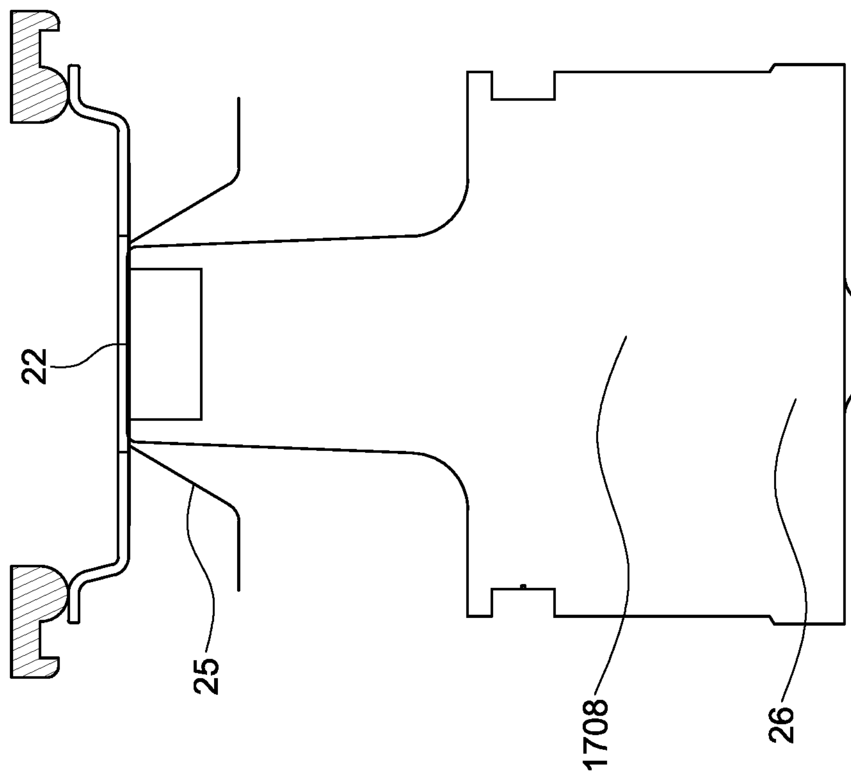


FIG. 90B

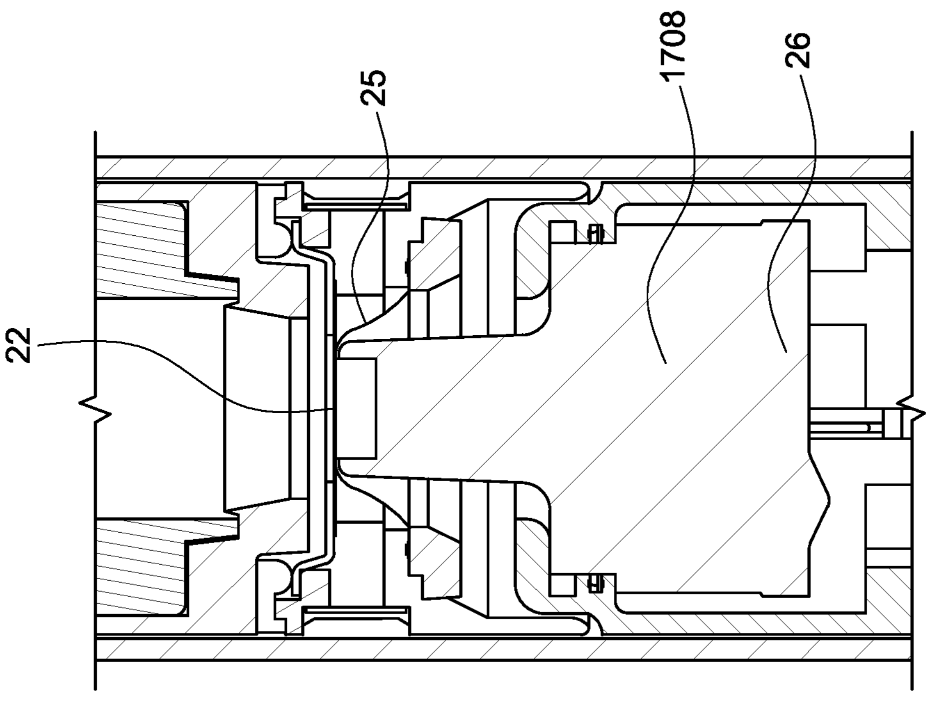


FIG. 90A

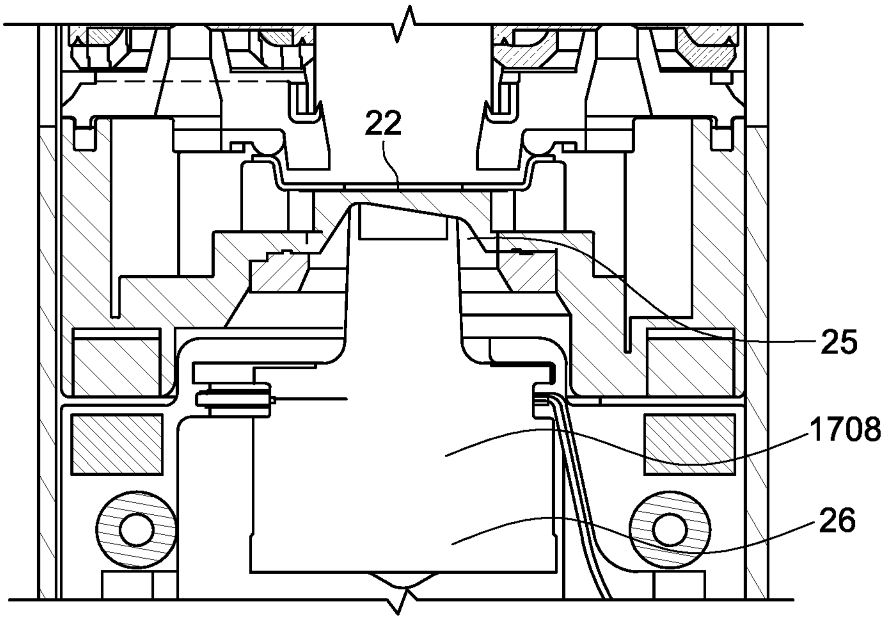


FIG. 91A

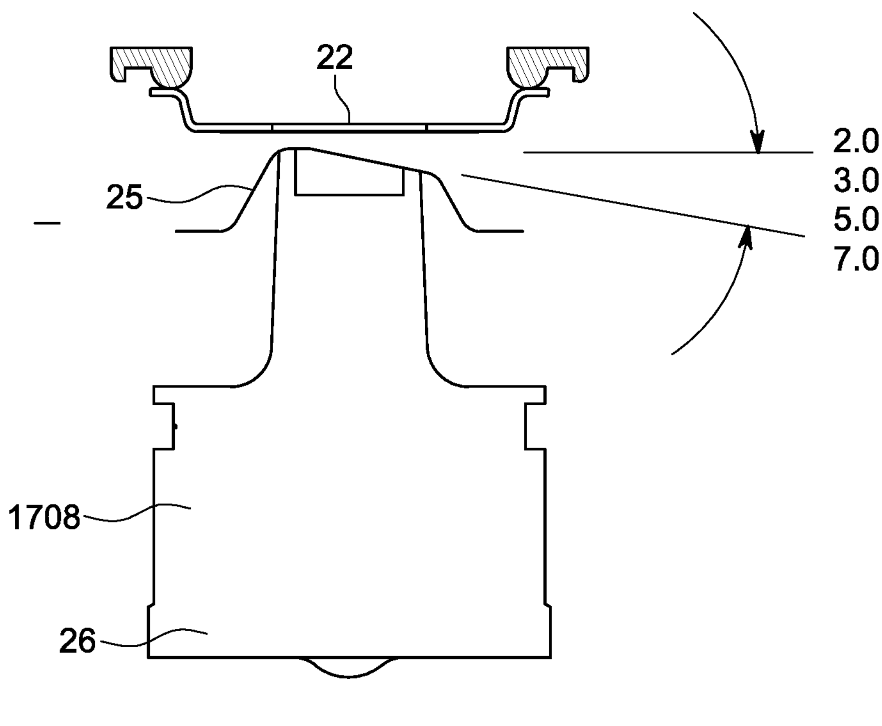


FIG. 91B

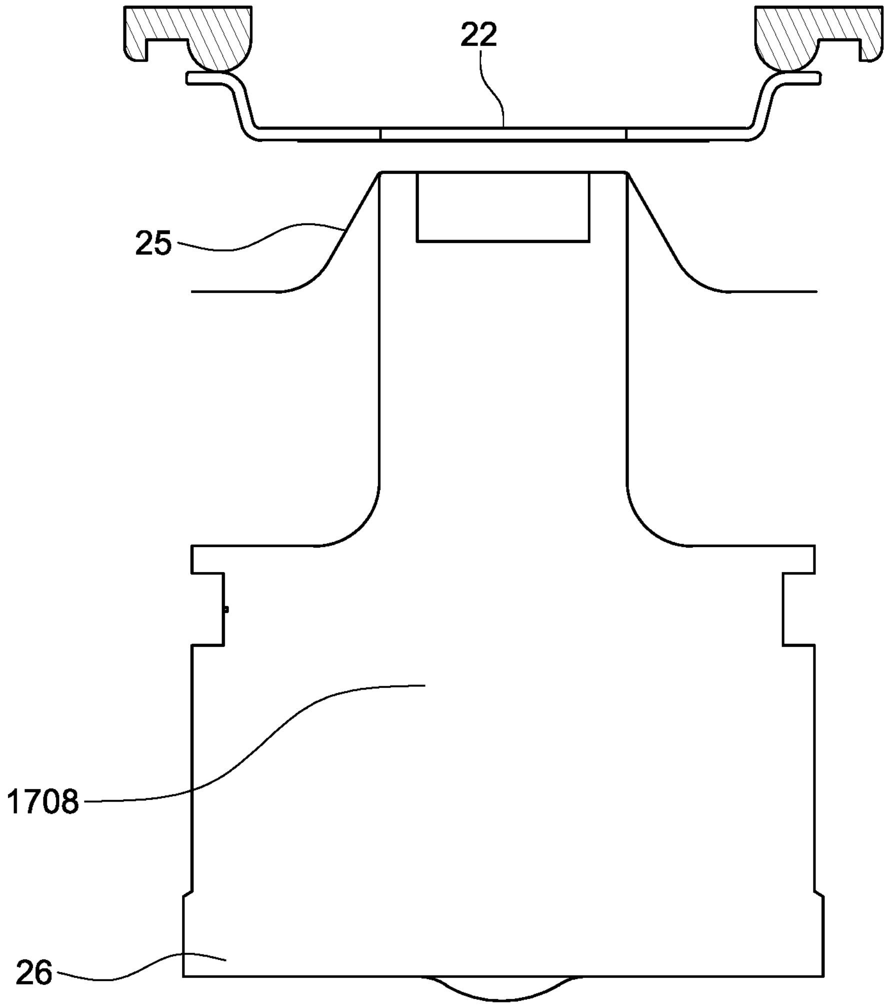


FIG. 92

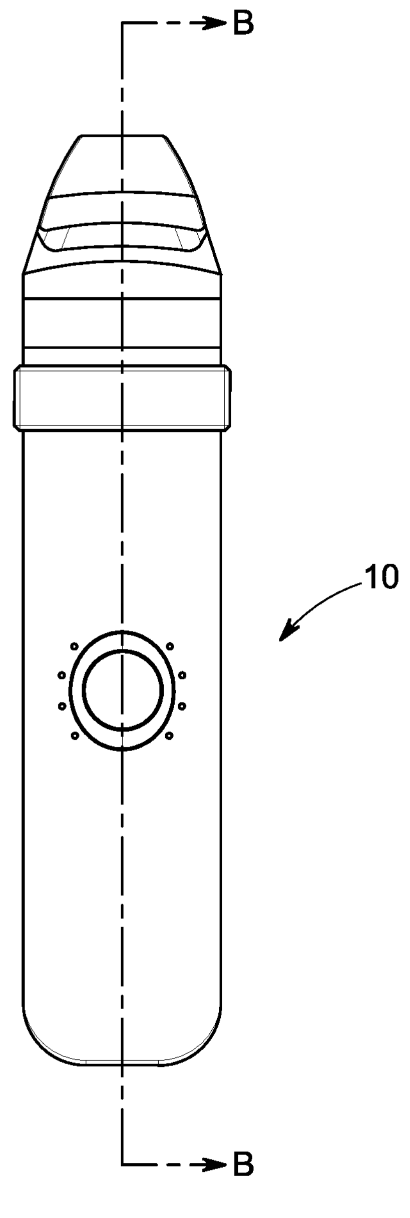


FIG. 93A

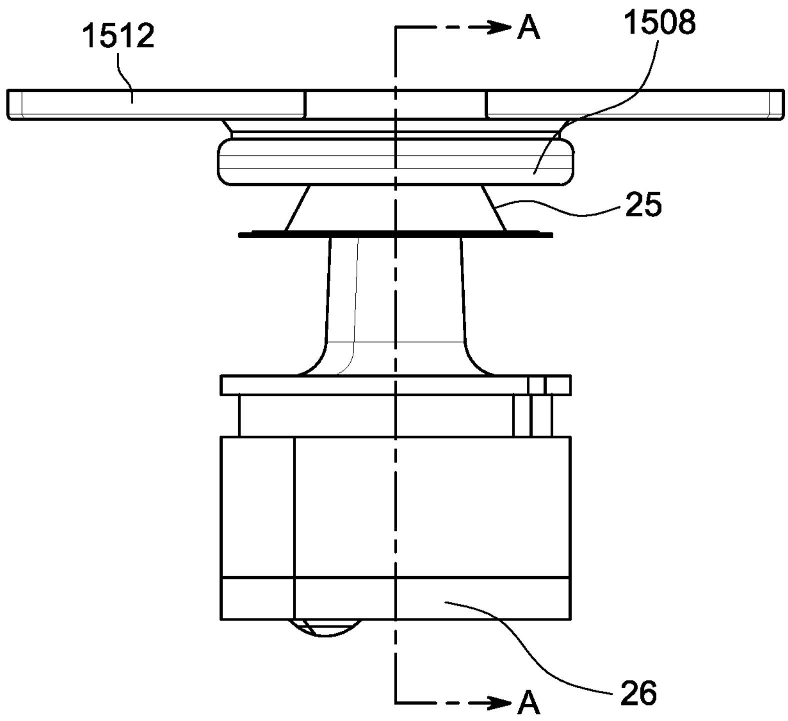
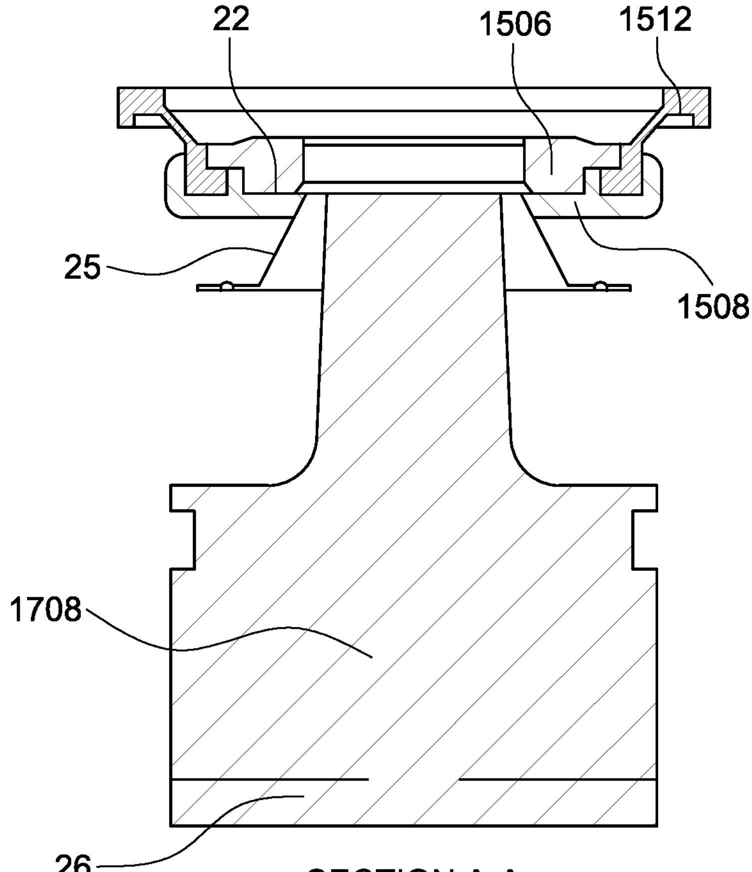


FIG. 93B



SECTION A-A
SCALE 4 : 1

FIG. 93C

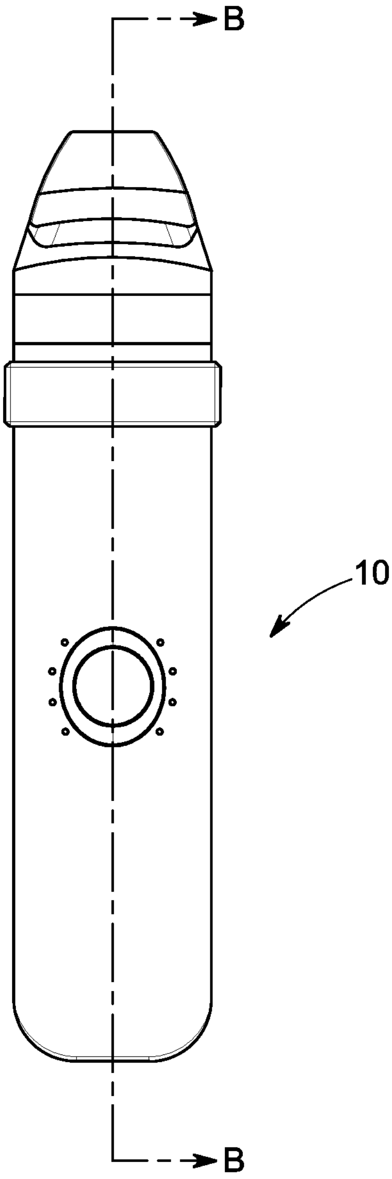
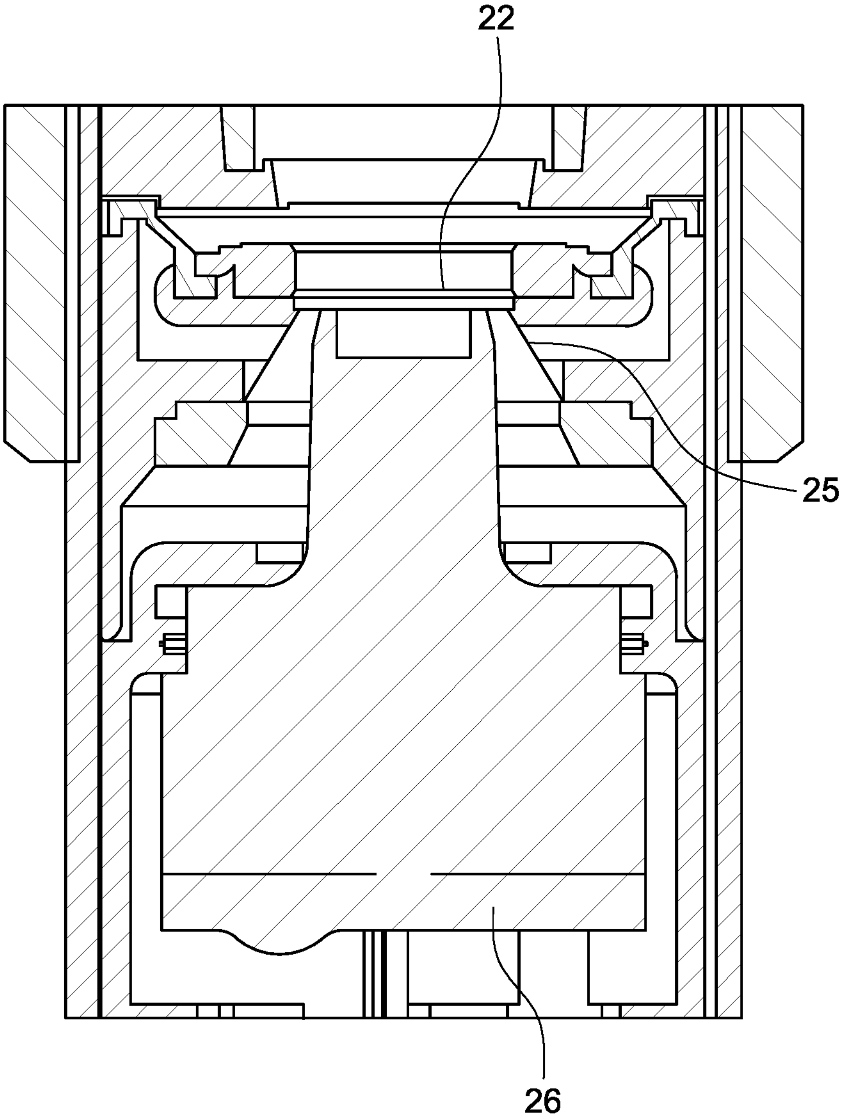


FIG. 94A



SECTION B-B
SCALE 4 : 1

FIG. 94B

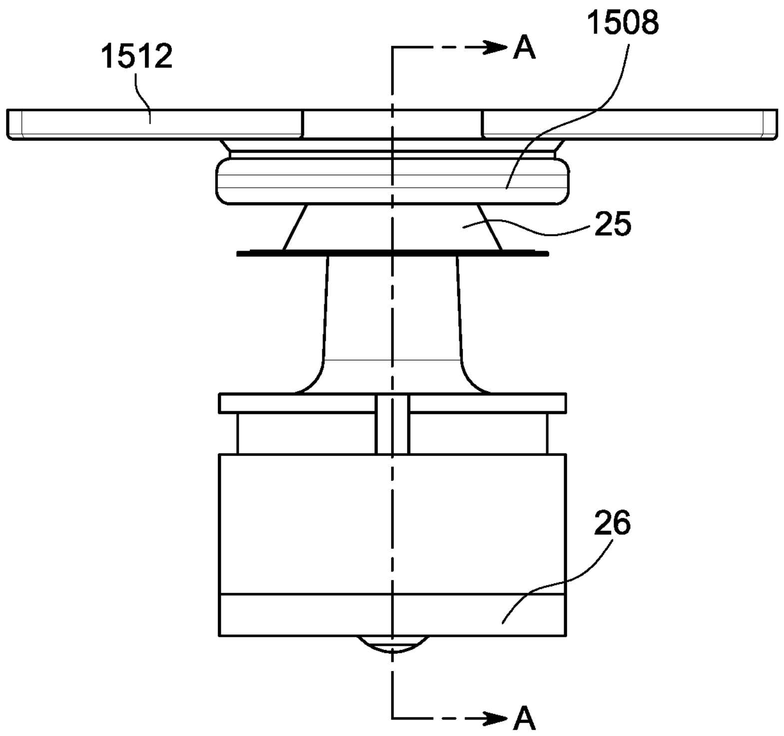
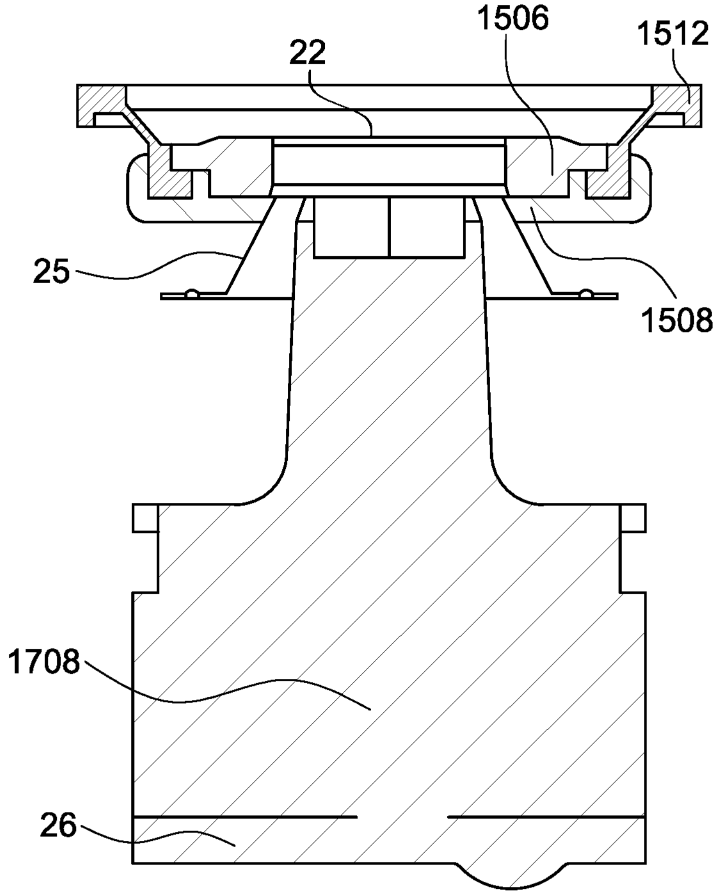


FIG. 94C



SECTION A-A
SCALE 4 : 1

FIG. 94D

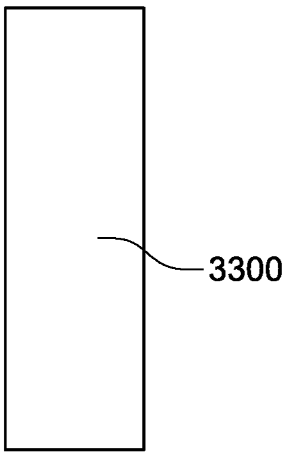


FIG. 95

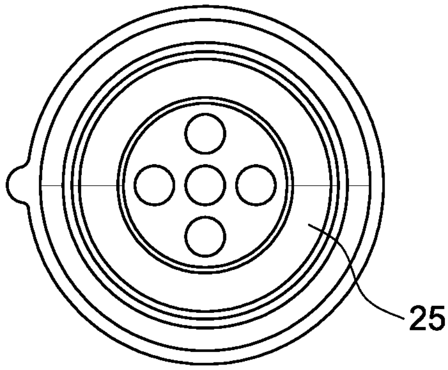


FIG. 96A

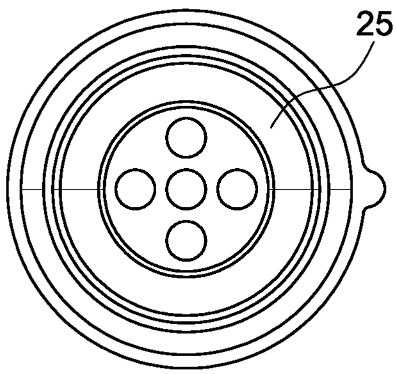


FIG. 96B

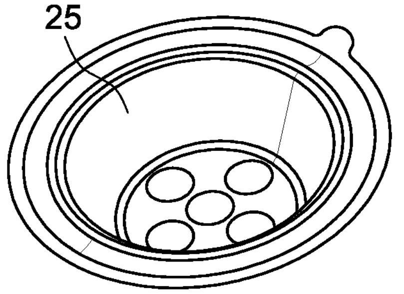


FIG. 96C

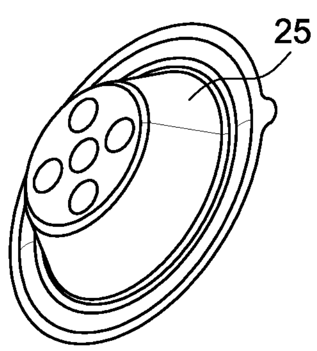


FIG. 96D

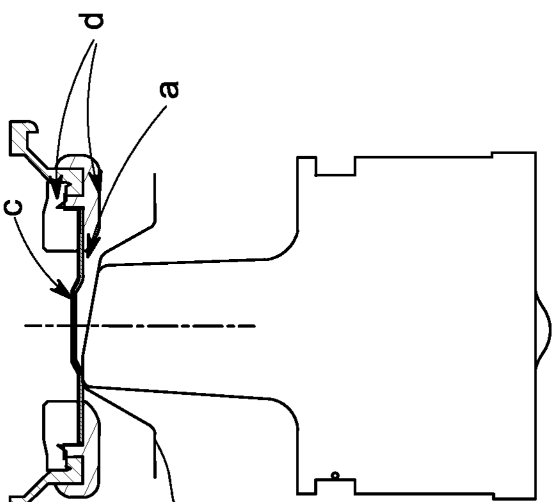


FIG. 97A

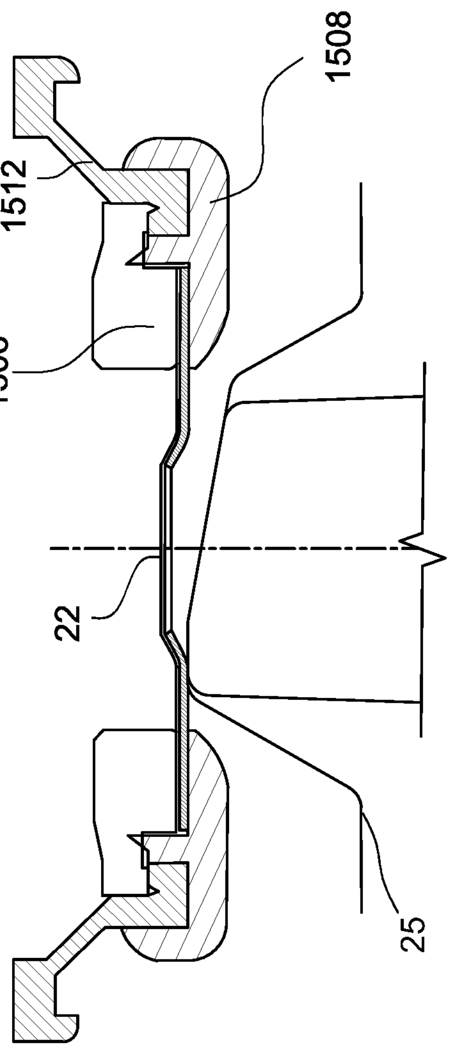


FIG. 97B

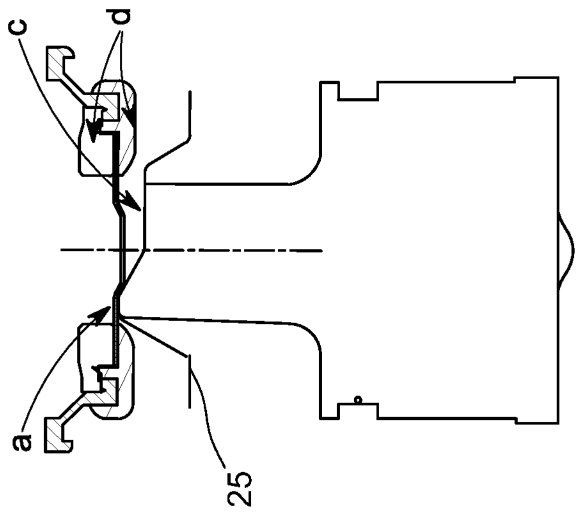


FIG. 98A

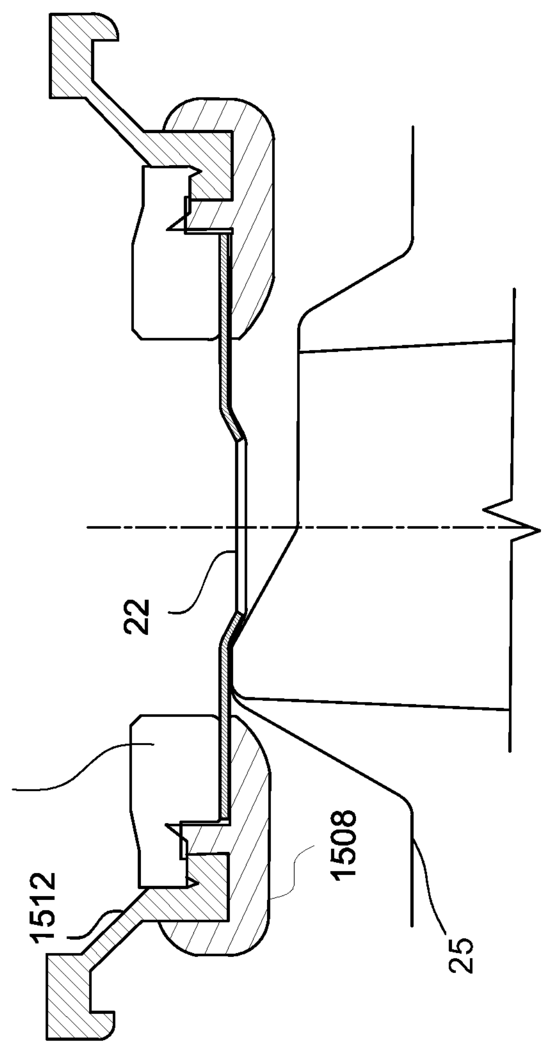


FIG. 98B

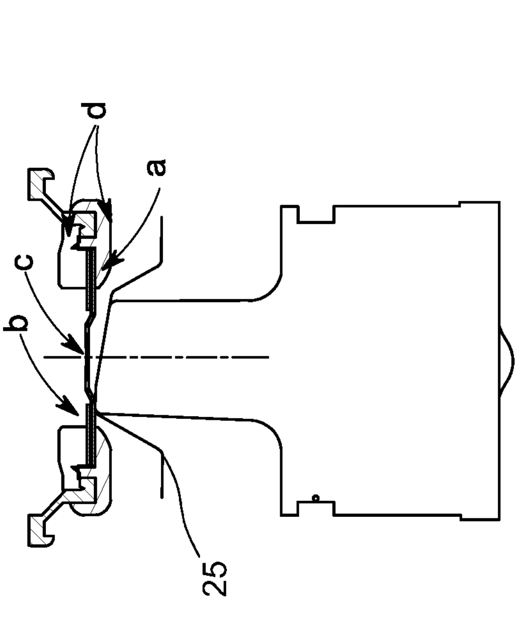


FIG. 99A

a:SUS316 L
b:SUS316 L
c:Polymer mesh
d:Plastic

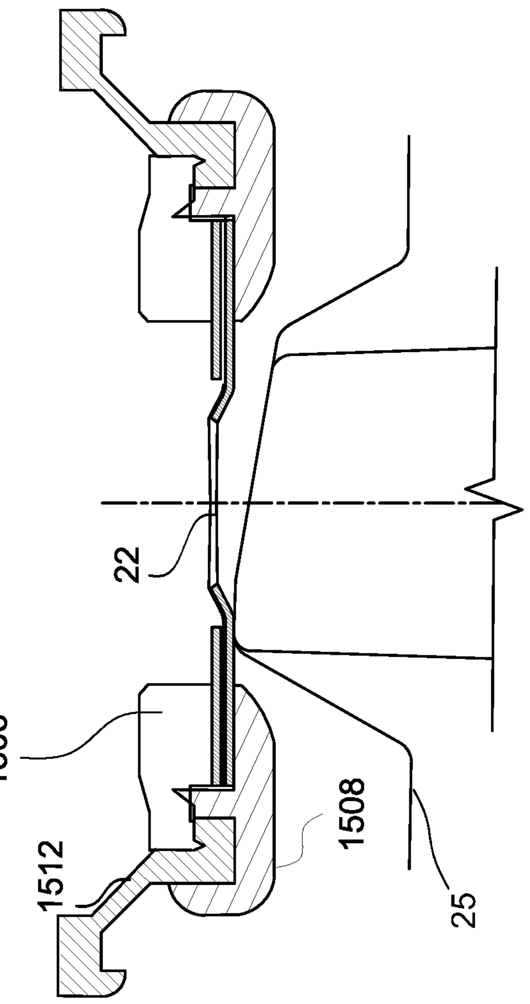


FIG. 99B

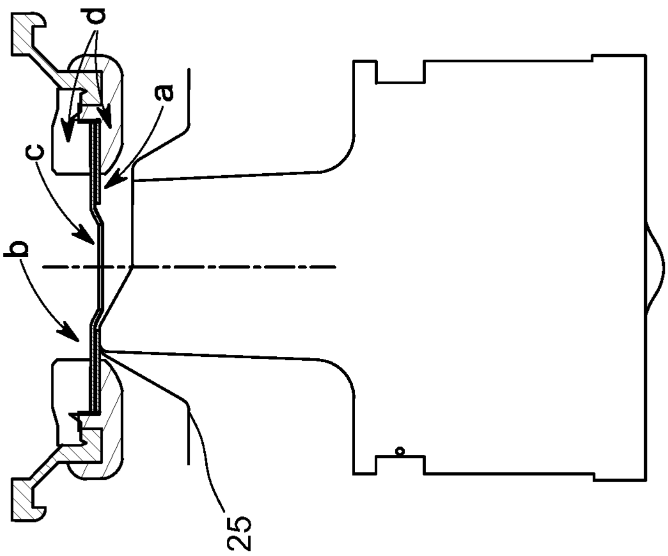


FIG. 100A

a:SUS316 L
b:SUS316 L
c:Polymer mesh
d:Plastic

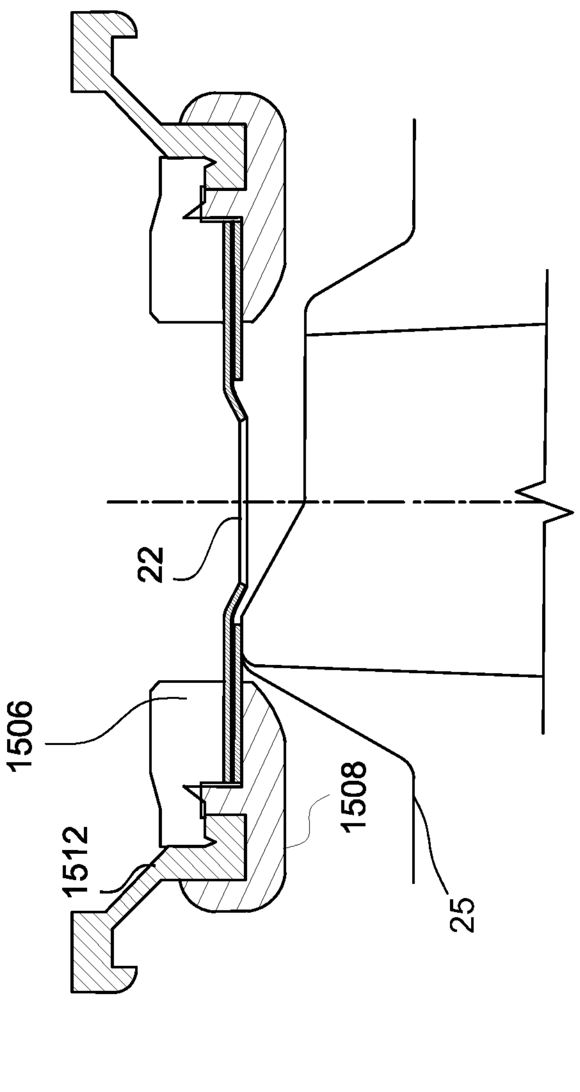


FIG. 100B

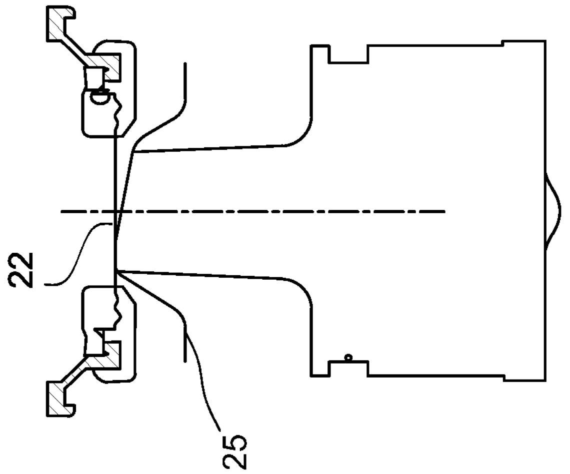


FIG. 101C

c:Polymer mesh
d:Plastic

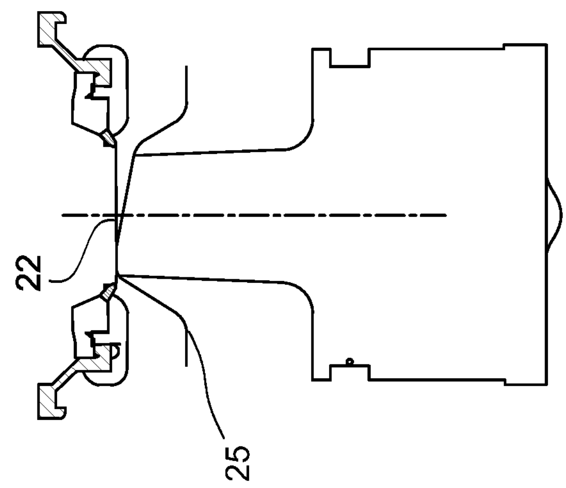


FIG. 101B

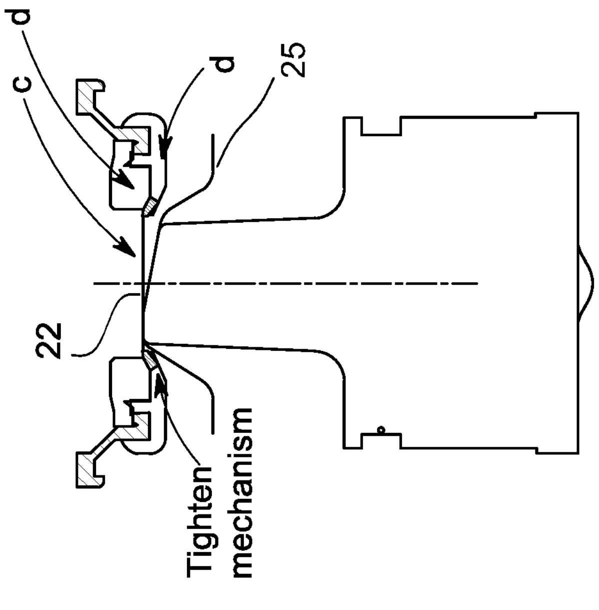


FIG. 101A

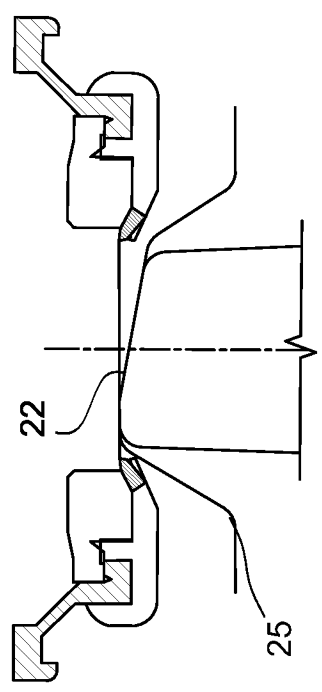


FIG. 102A

c:Polymer mesh
d:Plastic

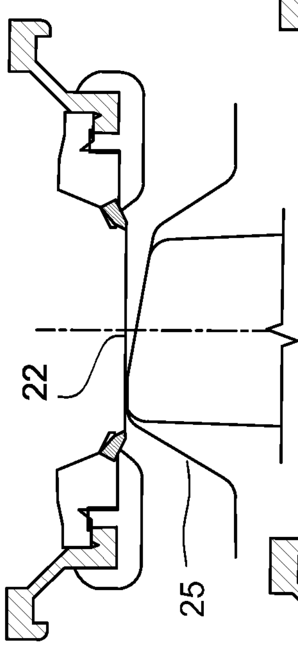


FIG. 102B

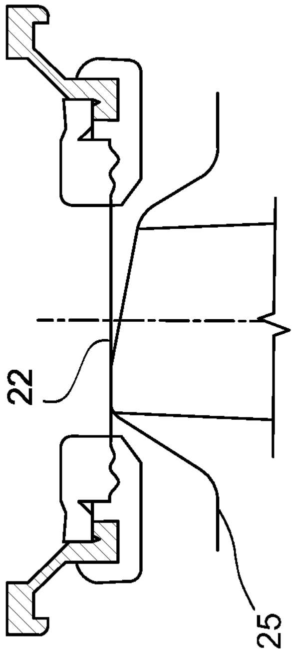


FIG. 102C

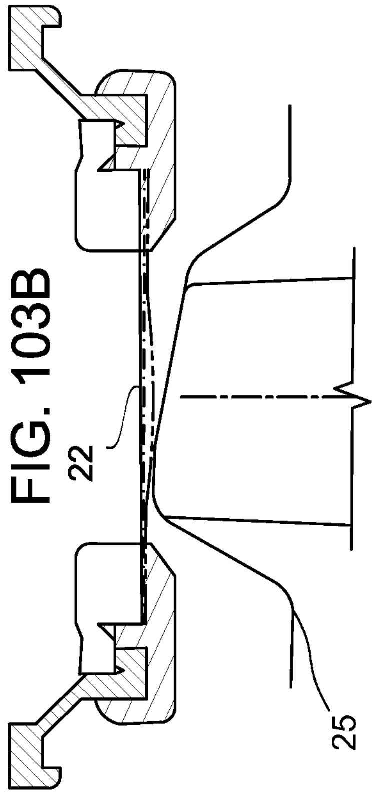


FIG. 103B

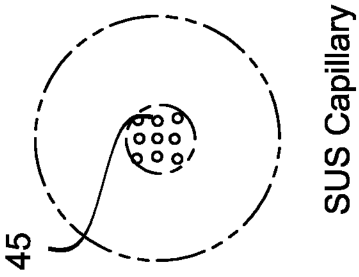


FIG. 103D

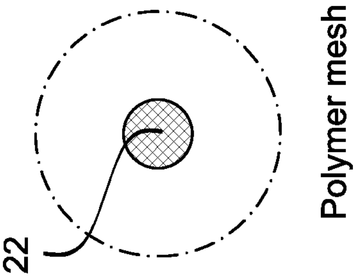


FIG. 103C

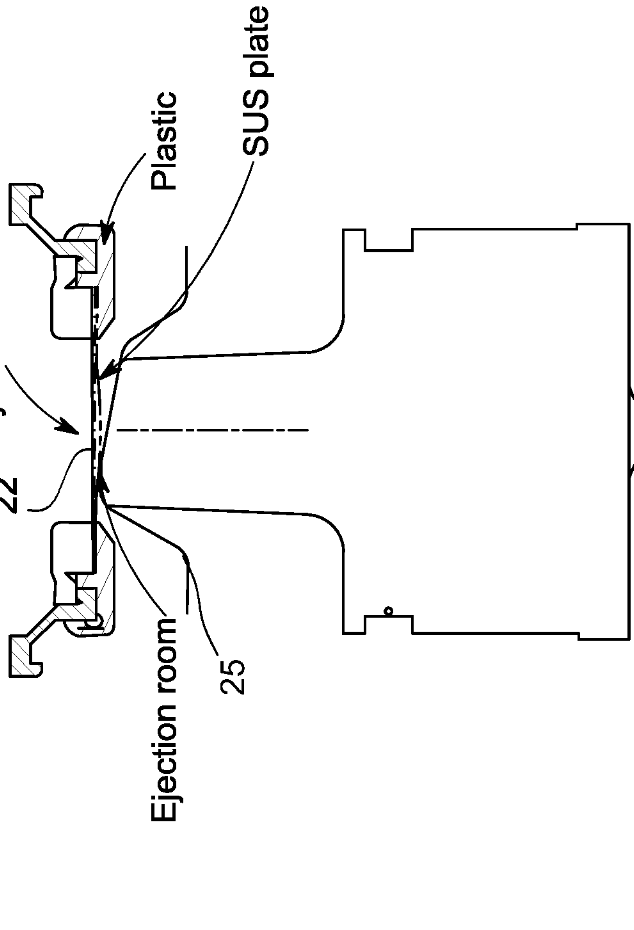


FIG. 103A

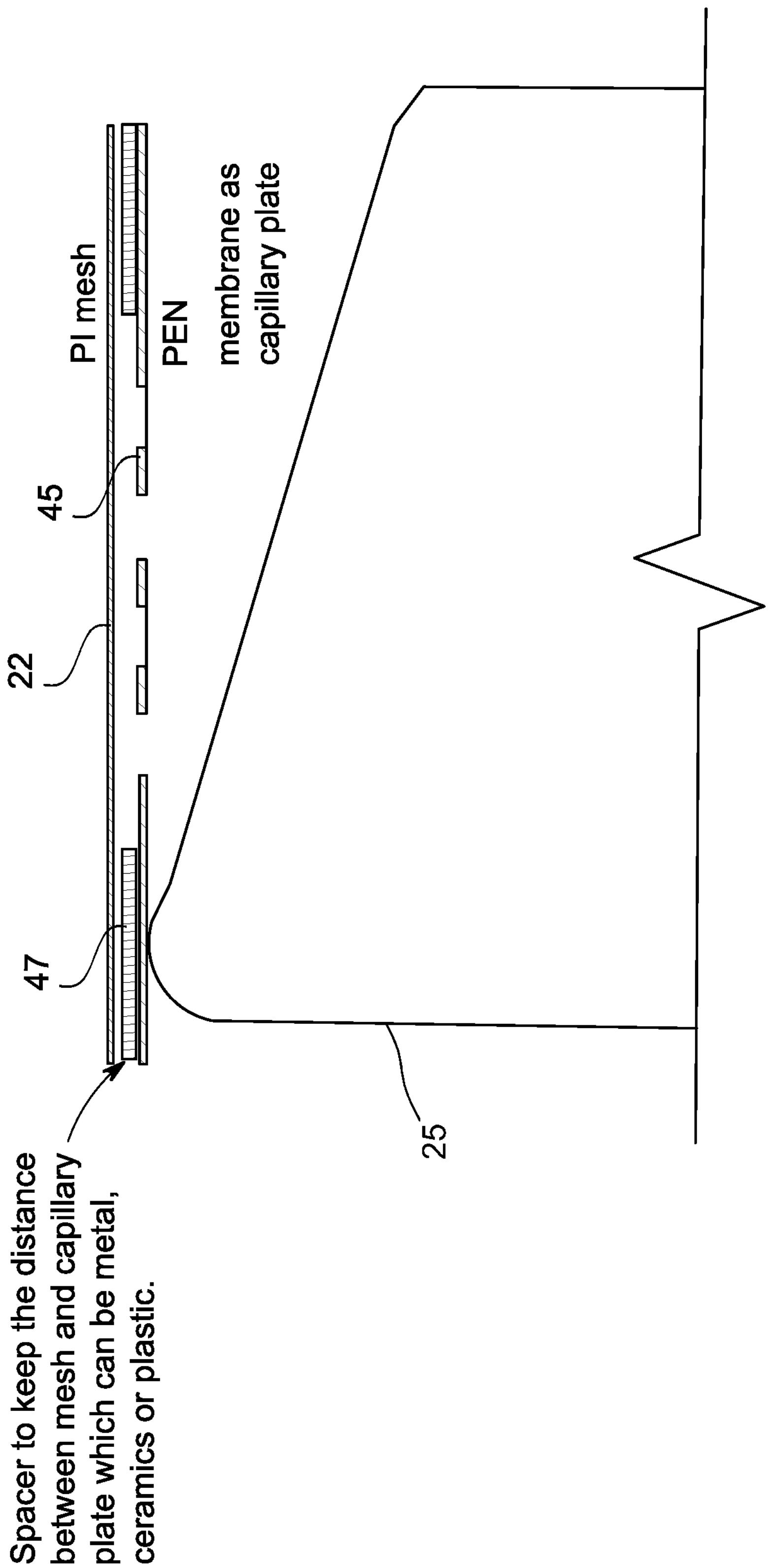

PI mesh
PEN
membrane as capillary plate
45
22
47
Spacer to keep the distance between mesh and capillary plate which can be metal, ceramics or plastic.
25

FIG. 104

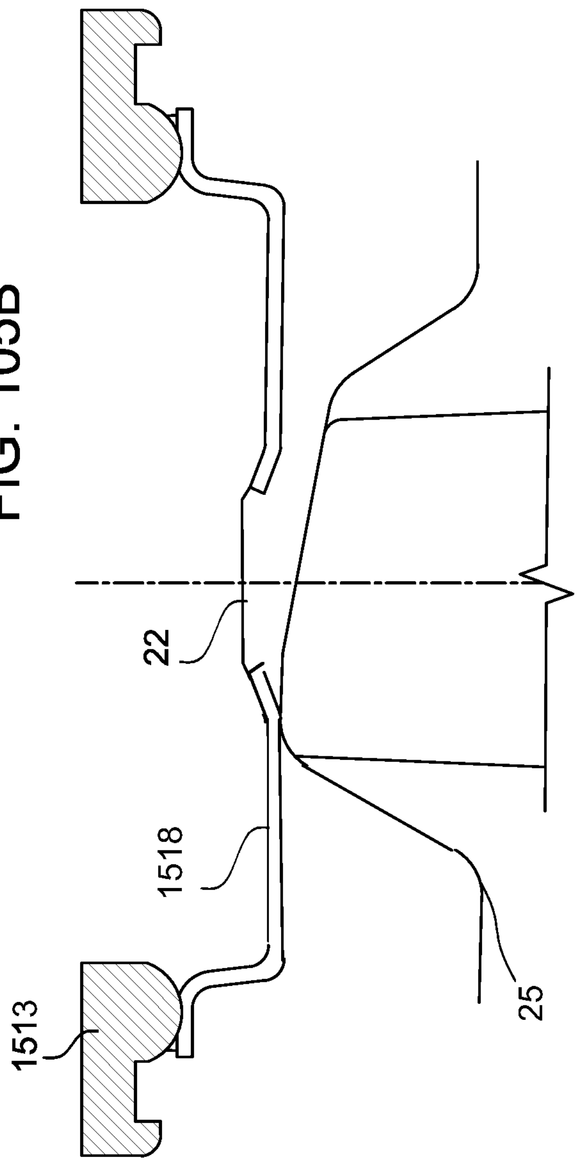


FIG. 105B

a:SUS316 L
c:Polymer mesh
d:Plastic

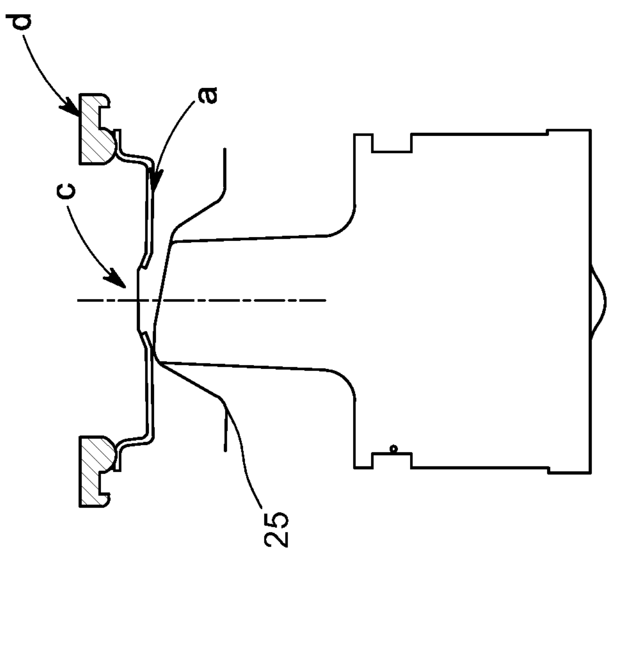


FIG. 105A

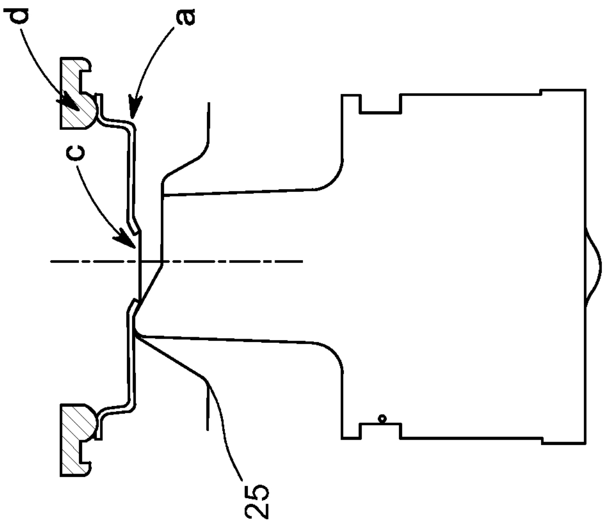


FIG. 106B

a:SUS316 L
c:Polymer mesh
d:Plastic

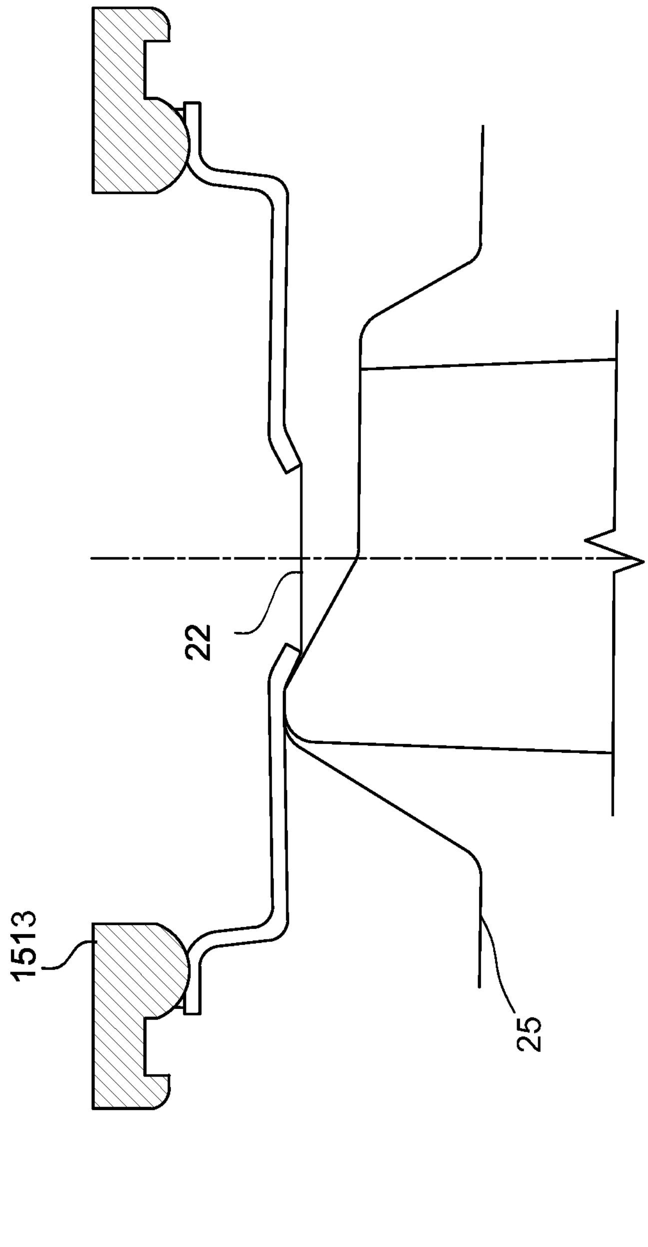


FIG. 106A

a:SUS316 L
b:SUS316 L
c:Polymer mesh
d:Plastic

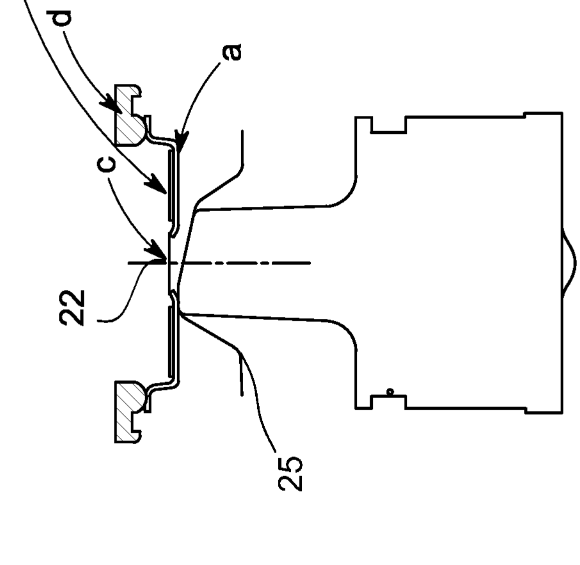


FIG. 107A

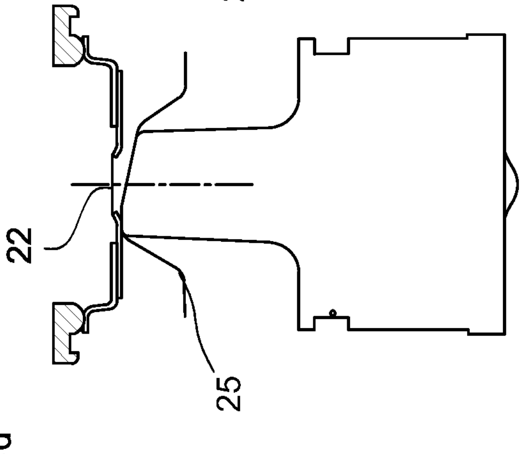


FIG. 107B

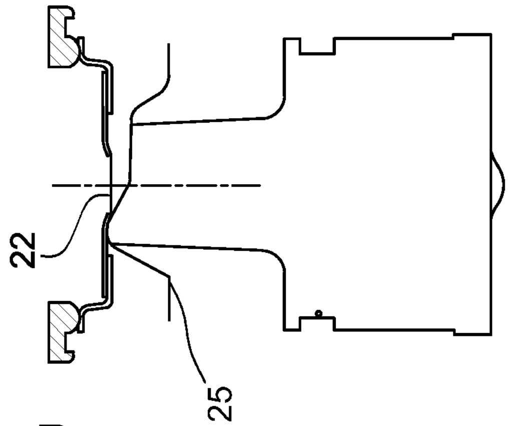


FIG. 107C

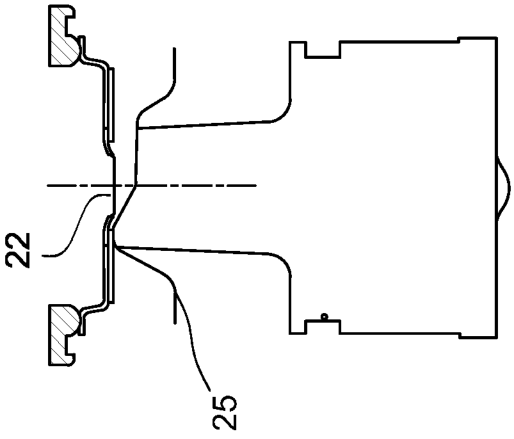


FIG. 107D

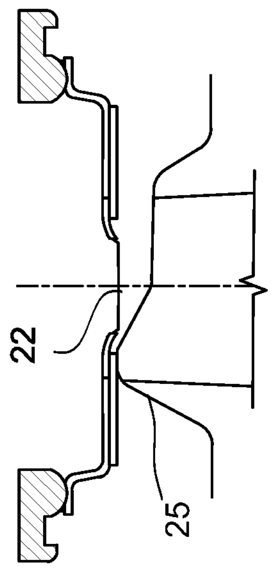


FIG. 108D

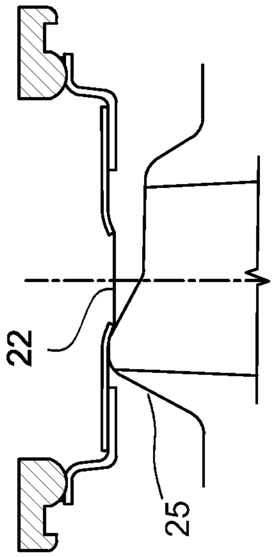


FIG. 108C

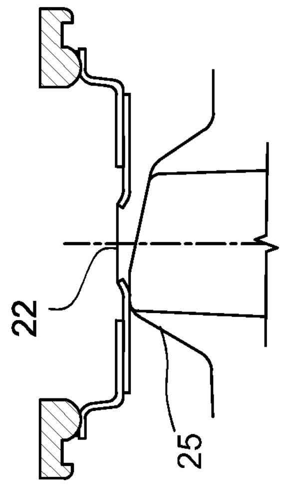


FIG. 108B

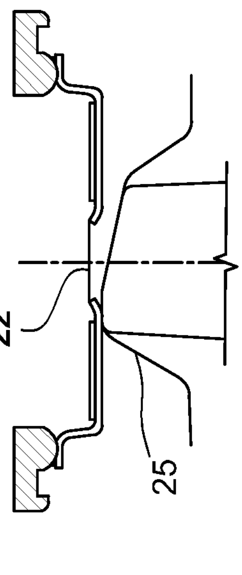


FIG. 108A

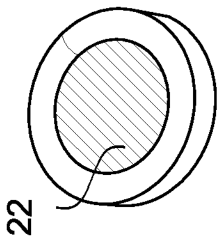
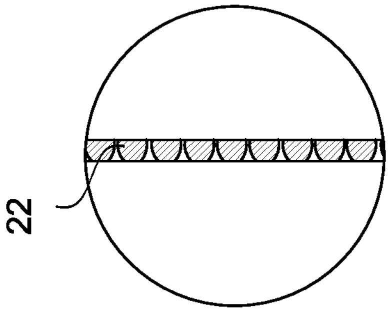


FIG. 109B



Section C-C

FIG. 109D

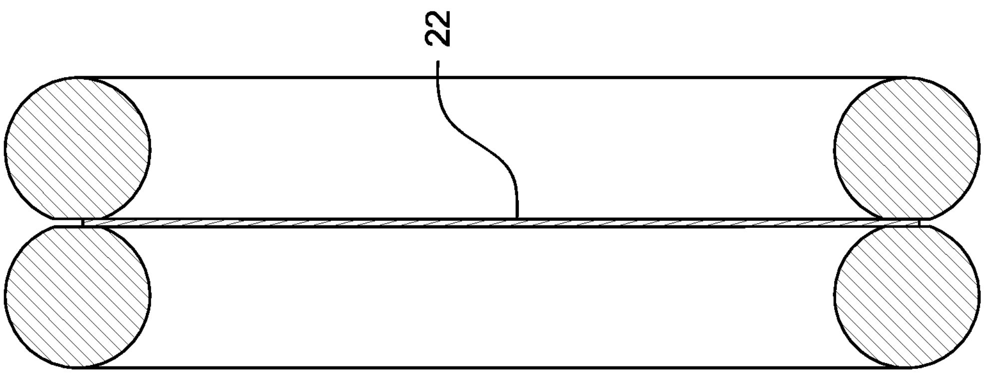


FIG. 109A

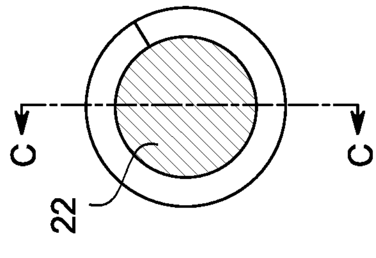


FIG. 109C

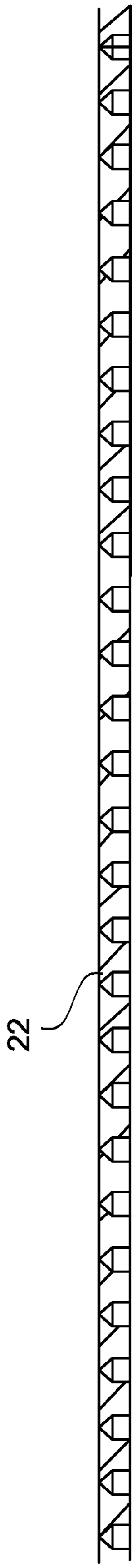


FIG. 110

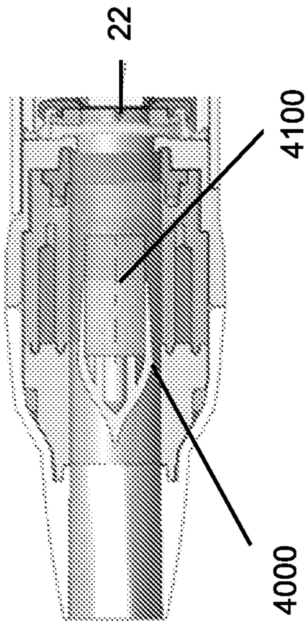


FIG. 111C

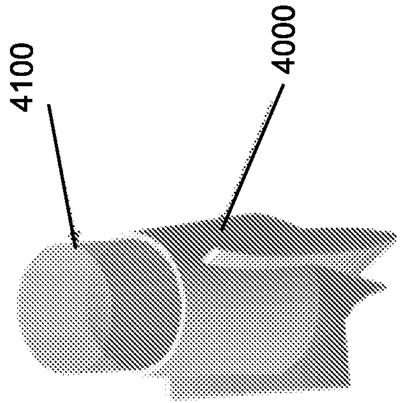


FIG. 111B

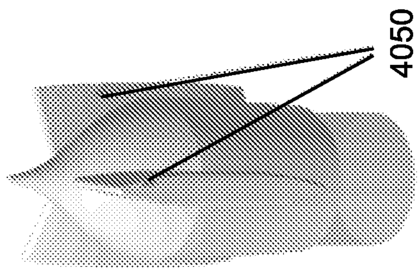


FIG. 111A

FIG. 112

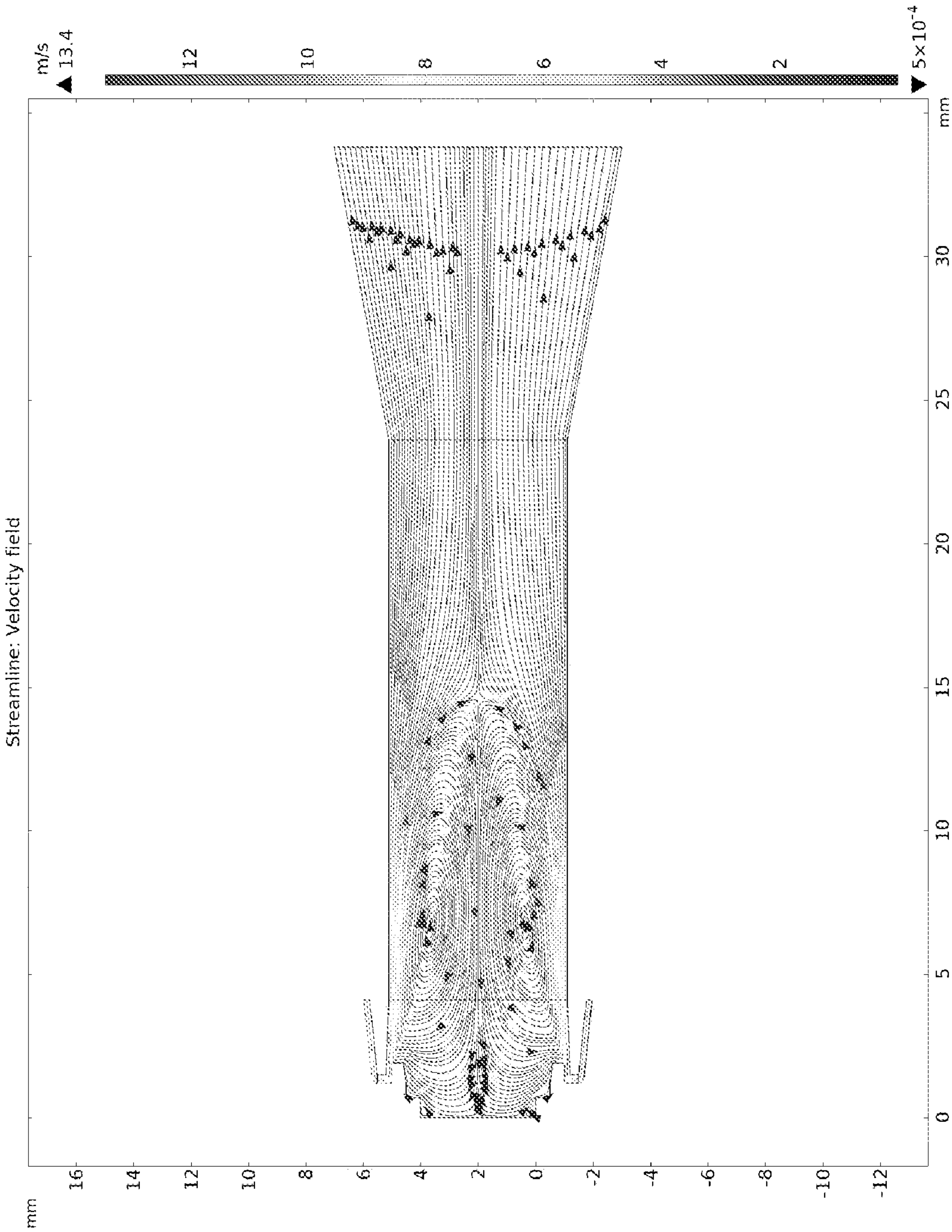

Streamline: Velocity field
m/s
13.4
12
10
8
6
4
2
5×10⁻⁴
mm
0
5
10
15
20
25
30
mm
16
14
12
10
8
6
4
2
0
-2
-4
-6
-8
-10
-12

FIG. 113

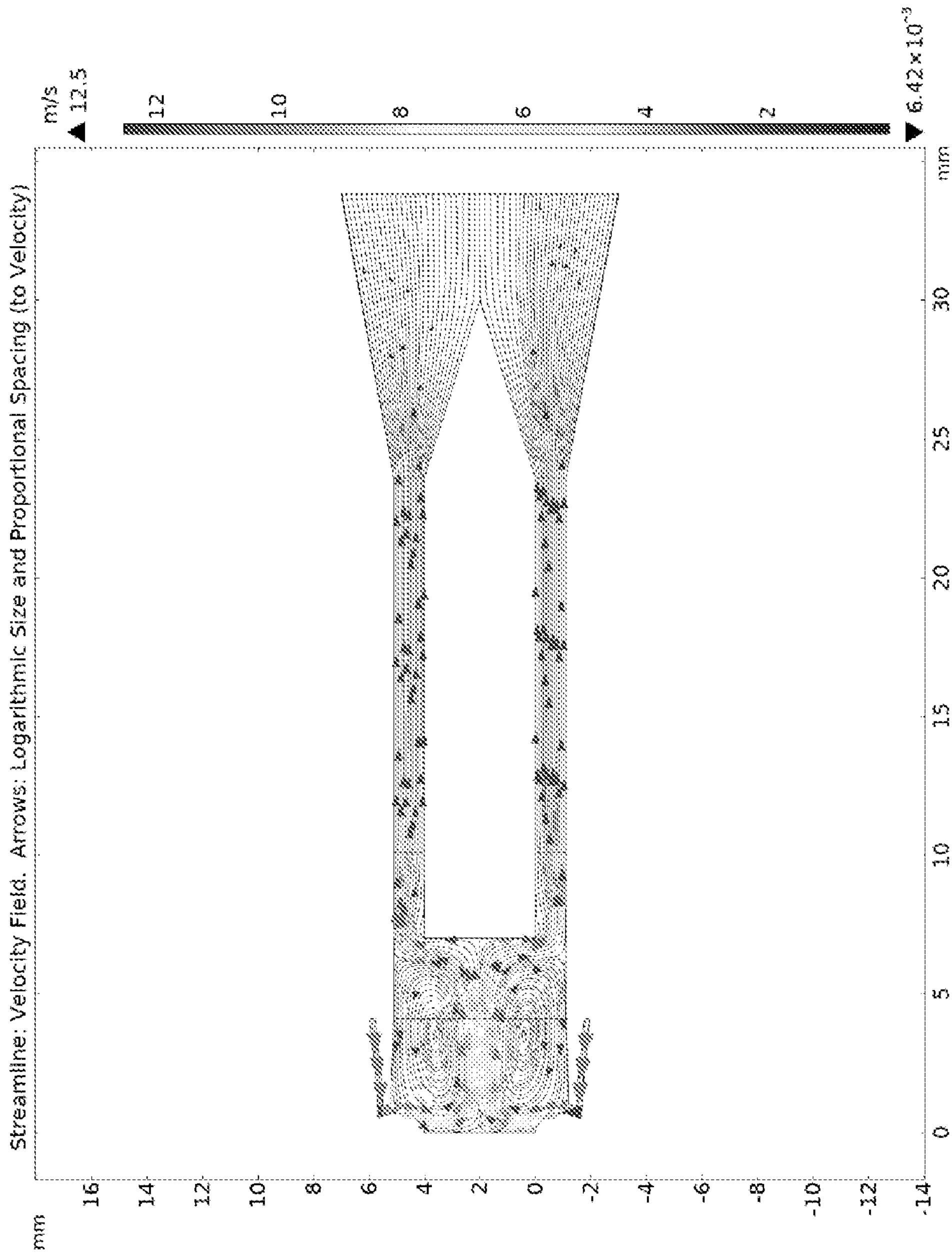
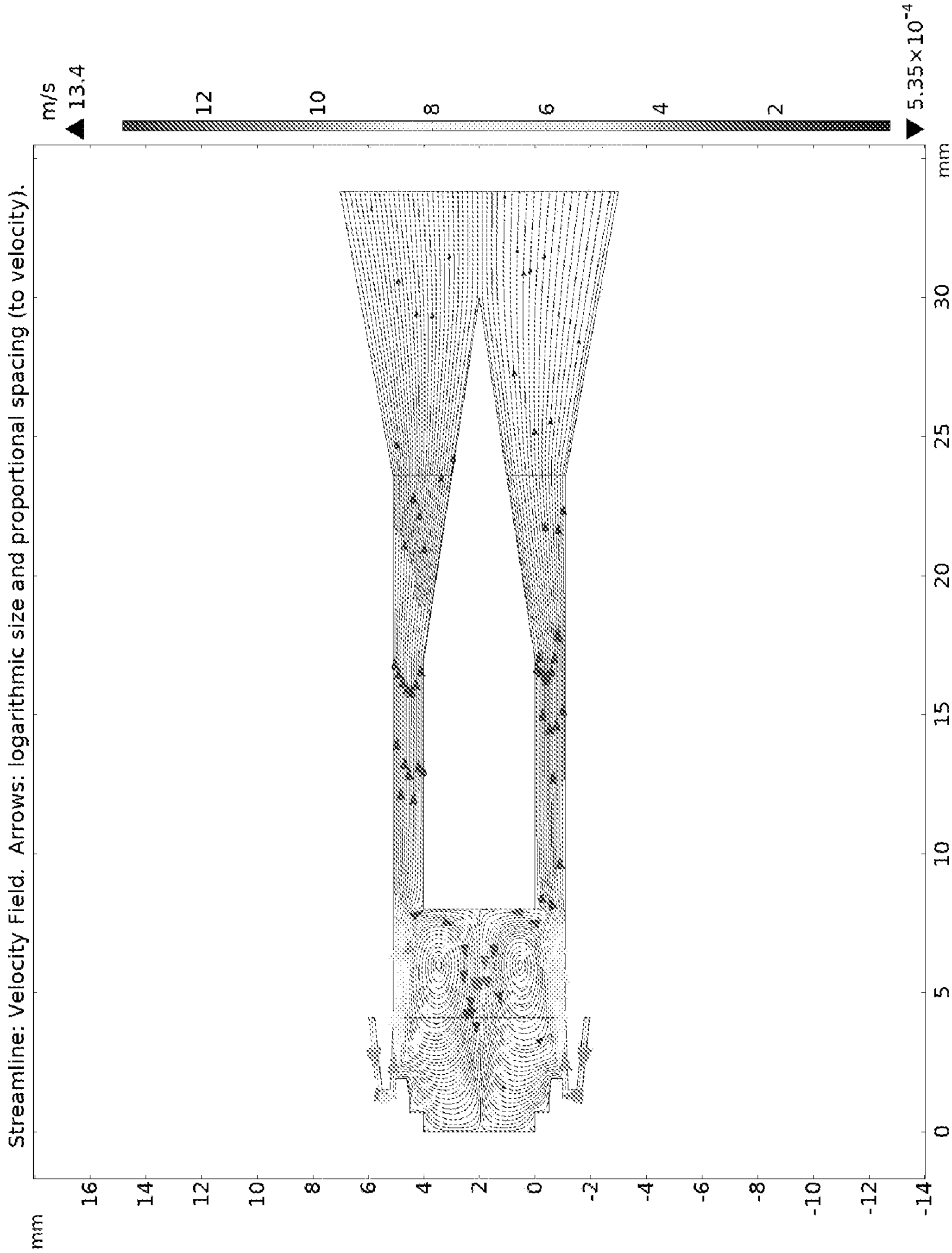

Streamline: Velocity Field. Arrows: Logarithmic Size and Proportional Spacing (to Velocity)
m/s
▲ 12.5
12
10
8
6
4
2
▼ 6.42×10⁻³
mm
16
14
12
10
8
6
4
2
0
-2
-4
-6
-8
-10
-12
-14
0
5
10
15
20
25
30
mm

FIG. 114


Streamline: Velocity Field. Arrows: logarithmic size and proportional spacing (to velocity).
m/s
13.4
12
10
8
6
4
2
5.35×10⁻⁴
mm
0
5
10
15
20
25
30
mm
16
14
12
10
8
6
4
2
0
-2
-4
-6
-8
-10
-12
-14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/034552

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M11/00 A61M15/00 A61M15/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2020/227717 A1 (PNEUMA RESPIRATORY INC [US]) 12 November 2020 (2020-11-12)	1-5, 8-19,21, 22, 27-33, 36-40, 42-45
A	abstract; figures 1-6 paragraphs [0046] - [0093] -----	6,7,20, 23-26,41
X	US 2020/230329 A1 (DANEK MARIO [US]) 23 July 2020 (2020-07-23)	1-5, 8-19,21, 22, 28-35, 39,43-45
A	abstract; figures 2-4 paragraphs [0154] - [0170] -----	6,7,20, 23-26,41
	-/--	

[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2022	11/10/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moraru, Liviu

2

International application No
PCT/US2022/034552

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8 616 195 B2 (POWER JOHN S [IE]; MORAN DECLAN [IE] ET AL.) 31 December 2013 (2013-12-31)	1-5, 8-19,21, 22, 27-33, 39,43-45
A	abstract; figures 1, 5, 6 column 4, line 23 - column 5, line 61 -----	6,7,20, 23-26,41

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/034552

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

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

1. [X] Claims Nos.: 46
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 46

Methods of providing medication to a subject as defined in claim 46 of the present application are methods for treatment of human or animal body by therapy. Indeed this method is meant to deliver fluids that are inhaled into mouth, throat, nose, and/or lungs (see paragraph 0002). Thus, claim 46 relate to subject-matter considered by this Authority to be covered by the provisions of Rules 39.1(iv) and 67.1(iv) PCT, and no international search report has been established with respect to the subject-matter of this claim (Article 17(2)(a)(i)PCT). Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i)PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2022/034552

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2020227717 A1	12-11-2020	AU 2020268879 A1	02-12-2021
		CA 3139686 A1	12-11-2020
		CN 113993631 A	28-01-2022
		EP 3965955 A1	16-03-2022
		IL 287891 A	01-01-2022
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		KR 20220030213 A	10-03-2022
		US 2022226587 A1	21-07-2022
		WO 2020227717 A1	12-11-2020
US 2020230329 A1	23-07-2020	NONE	
US 8616195 B2	31-12-2013	AU 2004258880 A1	03-02-2005
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		EP 3718585 A2	07-10-2020
		JP 4970938 B2	11-07-2012
		JP 2006528025 A	14-12-2006
		NO 336224 B1	22-06-2015
		US 2005011514 A1	20-01-2005
		WO 2005009323 A2	03-02-2005