



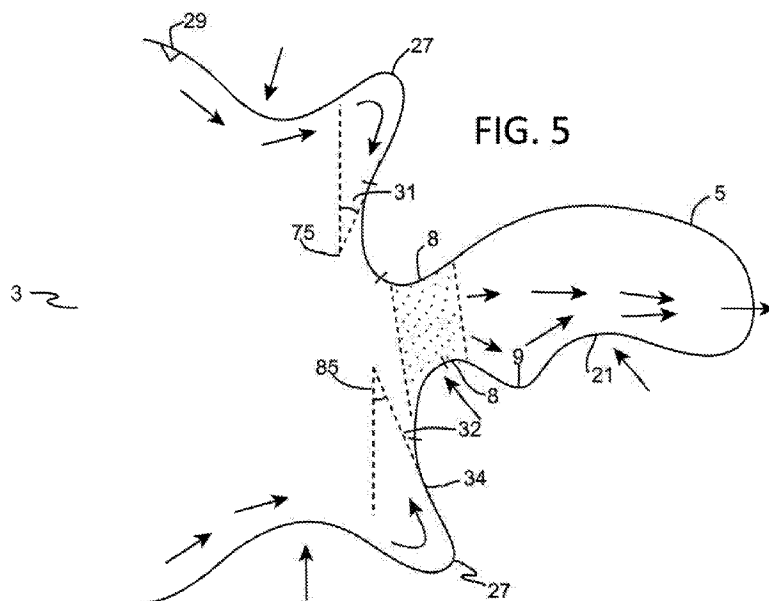
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(71) Demandeur/Applicant:
SAMANDARI, NAFYS, US
(72) Inventeur/Inventor:
SAMANDARI, NAFYS, US
(74) Agent: BORDEN LADNER GERVAIS LLP

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(54) Title: HYGIENIC AND ORTHOTROPIC ORAL DEVICES



(57) **Abrégé/Abstract:**

A hygienic oral pacification device includes a fluid-filled bladder. The bladder includes a nipple and alveolar ridge-mating flanges. The bladder is dynamically shaped and allows for pressures provided by the suckling child to re-shaping the bladder and flanges. A bite-block extends into the bladder to maintain a fluid path from nipple to flanges. As the child completes the suckling cycle, the bladder nipple is depressed and fluid is forced in the engorging flanges. The flanges thus cover the alveolar ridges and fill the vestibules. Further, a feed-bottle nipple includes an opening skirt to expand and rotate in the buccal vestibule. As the child completes the suckling cycle, the mouth portion is distorted, the skirt extended to provide cleaning, stimulation, and a bumper to deny extensive pronation. The flanges and skirt may be covered with a textured surface, or bristles, that provide mechanical brushing of oral surfaces.

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(72) Inventor; and

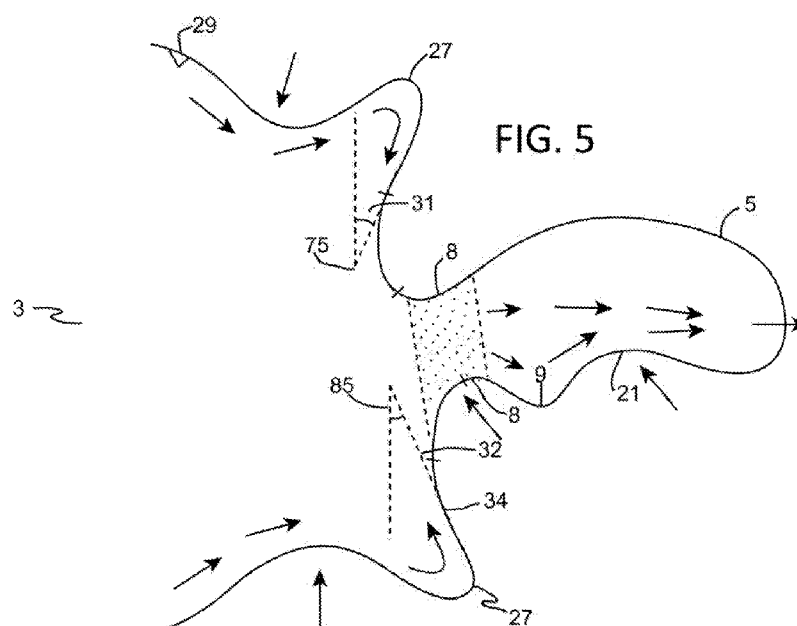
(71) Applicant: SAMANDARI, Nafys [US/US]; 6945 E Sahuaro Dr. #A3, Scottsdale, AZ 85254 (US).

(74) Agent: BYCER, Matthew, L.; Bycer Law, PLC, 7220 N. 16th Street, Suite H, Phoenix, AZ 85020 (US).

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(54) Title: HYGIENIC AND ORTHOTROPIC ORAL DEVICES



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HYGIENIC AND ORTHOTROPIC ORAL DEVICES

CLAIMS OF PRIORITY

The present application includes subject matter disclosed in and claims priority
5 to U.S. patent application Serial No. 16/711,128, filed December 11, 2019, entitled
"Hygienic and Orthotropic Oral Devices"; and application Serial No. 16/383,223, filed
April 12, 2019, entitled "Pacifier with Cleaning Brush" (now U.S. Patent No.
10,555,876); and also provisional patent application entitled "Improved Pacifier and
Nipple" filed July 11, 2019 and assigned Serial Number 62/872,900, incorporated
10 herein by reference, which describe inventions made by the present inventor.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the general art of oral care. The present
15 invention more particularly relates to a pediatric dental oral hygiene and orthotropic
development devices and uses thereof.

2. Description of Related Prior Art

Improvements to the BINKI BRUSH, or pacifier with cleaning brush, may be
20 used on pacifiers, bottle nipples, or other devices intended for use in a mouth. Children
from the age of zero to two years commonly use oral apparatus, such as pacifiers, bottle
nipples, teethingers, etc. for numerous purposes. As may be understood from the name
"pacifier", the tool may be used to calm or soothe a child. Additionally, the tool may

be used to exercise a child's tongue and cheek muscles, promote development of the maxilla, and otherwise serve to clean interior surfaces of the oral cavity via friction provided by the pacifier exterior surface(s). While newborns are often born without any erupted teeth, up to 15% of newborns in the United States have one or more teeth present. The "baby" tooth or teeth may be compromised due to decay caused by bacterial metabolic byproducts such as acids produced from substances in the oral cavity such as sugars present in milk, formula, or otherwise the tooth/teeth may be susceptible to damage from bacterial and fungal biofilms that may develop on the oral surfaces. It is therefore advantageous to include an oral apparatus that acts to clean, or otherwise brush, the upper and lower gingival ridges and/or erupted teeth. In addition, it has been shown that in the year 2014, approximately 40% of children under the age of 5 have some evidence of caries, often referred to as baby bottle caries.

Most oral apparatus, such as pacifiers, binkies, soothies, etc., are often symmetrical. Oftentimes, a binky, or surrogate nipple, may be uniformly isometric, such as including a cylindrical nub with hemispherical cap (imitating a mother's biological nipple). Advanced oral devices may be transversely symmetrical, left to right, however, may include longitudinal shape changes such as alternating superior and inferior sides to better mimic the shape and location of the tongue, and the slight overbite of a baby, newborn, infant, or toddler. The promotion of an ideal orthotropic development of the maxillary and mandibular arches leads to the better development of the airway spaces, and this contributes to the prevention of multiple chronic maladies. As known in the field of orthotropics, deficiencies in airway spaces exacerbate these chronic conditions.

Prior attempts have been made to provide oral devices that achieve the dual purpose of pacification and oral hygiene, however, they suffer the drawbacks of improperly accounting for the changing shape of the mouth during the suckling exercise. Further, limited inventions have been directed to orthotropics and improvement of the development of the upper palate and/or mandible in the developing mouth. Nine out of ten children in the developed world may suffer some level of obstructive sleep apnea (OSA), including symptoms from sleep disorders, to breathing issues, to growth retardation.

It is therefore a primary object of the present invention to provide an oral device that provides for friction activated cleansing and/or stimulation of interior oral surfaces.

It is another object of the present invention to provide a pacifier to mate with at least one of the superior or inferior ridges (gingival and/or tooth).

It is yet another object of the present invention to foster proper development of the orthognathic relationship of the upper and lower jaw bones.

It is as yet a further object of the present invention to foster proper development of the upper palate and related bone structures.

It is a further object of the present invention to provide an easy to use oral device useful for babies and/or small children.

These and other objects of the present invention will become apparent to those skilled in the art as the description thereof proceeds.

SUMMARY OF THE INVENTION

The present invention is also directed to an oral device adapted to be partially inserted into the oral cavity. The present invention may take the form of a pacifier, bottle nipple, or otherwise. As a pacifier, the shield set on the outer surface of the lips, and the nipple, with flanges/wings emplaced within. When functioning as a bottle feed nipple, as single molded piece is preferred to fit over an open end of a bottle.

In the previous version, the upper portion of the intra oral device includes a preferably solid and/or flexible padding with one or more materials. Harder or thicker portions of the dome (or pads) will be separable, or at least change their relative orientation, as the central material stretches. A central bite block, as well as shield and/or cap may be made of one or more stiffer material(s). As the sucking motion is conducted, a tongue pressure pushes up on the bottom of the nipple (preferably at the tongue guide depression) and causes lateral stretching of the device. As the device is stretched, the harder/thicker portions at the top side resist stretching and are thus thrust against the upper palate and cause a slight upward and laterally outward force. The lower portion includes a tongue depression to better ensure proper alignment of device with the center of mouth and tongue. The outer surface of the device may include bristles, or a spiral shape for cleaning purposes, often as rubbed against surfaces of the mouth.

A nipple version of the present invention may include various undulations, and/or ribs, to cause proper turbulence of flowing fluids, to provide stimulation/cleaning to the oral surfaces, and to prevent vacuum seals on the mouth surfaces, and avoid hematomas. The angle of the pronation of the teeth and/or alveolar

ridges is prevented from exceeding certain thresholds, e.g. 20% pronation that can cause adverse deformation of the malleable (growing) jaws. Further, the superior and inferior edges of the device, preferably at the collar, are offset with the superior set slightly (e.g. 1-3mm) forward relative the inferior collar to promote proper orthotropic alignment of the maxilla and mandible relative the skull.

The present invention is directed to an oral pacification device adapted to be partially inserted into the oral cavity, with the shield set on the outer surface of the lips, and the nipple, with flanges/wings emplaced within. There are two components to the device -- an extra-oral base piece and an intra-oral nipple. The intra-oral part includes a bladder formed within an exterior shell. The bladder includes an interior that is a fluid-filled chamber. The bladder forms the nipple that extends posteriorly with flanges/wings set on the bladder outer surface at the anterior end. It is contemplated that the flanges be set against the anterior surfaces of the alveolar ridge(s) and wings set posterior the ridges. The chamber has a passage opening from the nipple bulb and into the flanges/ wings. Preferably the bladder is a single fluid filled chamber, but it may be sectioned. The shell of the bladder includes an outer surface that has surface features, such as a texture, fingers, bristles, etc. The textured surface may be set in direct contact with the ridges (either bare gums (edentulous), or with erupted teeth). In alternative embodiments, the textured surface may also extend along the inferior surface of the nipple and bulb to provide for cleaning of the top of the tongue, and along superior surface to clean the roof of the mouth / hard palate.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be described with greater specificity and clarity with reference to the following drawings, in which:

Figure 1 illustrates a side cross-sectional view of a bottle embodiment in
5 passive state as applied into a human mouth.

Figure 2 illustrates a side cross-sectional view of a bottle embodiment in a compressed state as applied into a human mouth.

Figure 3 illustrates a side cross-sectional view of the mouth portion in passive state of a bottle embodiment of the present invention.

10 **Figure 4** illustrates a frontal view of a nipple in passive state of a bottle embodiment of the present invention.

Figure 5 illustrates a side cross-sectional view of the mouth portion in compressed state of a bottle embodiment of the present invention.

15 **Figure 6** illustrates a frontal view of a nipple in compressed state of a bottle embodiment of the present invention.

Figure 7 illustrates a top view of a mouth portion in passive state of a bottle embodiment of the present invention.

Figure 8 illustrates a frontal view of a nipple and skirt in passive state of a bottle embodiment of the present invention.

20 **Figure 9** illustrates a cross-sectional side view of a skirt and collar in passive state a bottle embodiment of the present invention.

Figure 10 illustrates a top view of a mouth portion in compressed state of a bottle embodiment of the present invention.

Figure 11 illustrates a frontal view of a nipple and skirt in compressed state of a bottle embodiment of the present invention.

Figure 12 illustrates a cross-sectional side view of a skirt and collar in compressed state a bottle embodiment of the present invention.

5 **Figure 13** illustrates a side view of a bottle embodiment of the present invention.

Figure 14 illustrates a perspective view of a bottle embodiment of the present invention.

10 **Figure 15** illustrates a top view of a mouth portion of a bottle embodiment of the present invention.

Figure 16 illustrates a frontal view of a mouth portion of a bottle embodiment of the present invention.

Figure 17 illustrates a bottom view of a mouth portion of a bottle embodiment of the present invention.

15 **Figure 18** illustrates a perspective view of a mouth portion of a bottle embodiment of the present invention.

Figure 19 illustrates a side cross-section view along lines A-A of FIG. 16.

Figure 20 illustrates a side cross-section view along lines B-B of FIG. 16.

20 **Figure 21** illustrates a side cross-section view along lines BB of FIG. 16 as when the mouth portion is in a compressed state.

Figure 22 illustrates a side view of a mouth portion of a bottle embodiment of the present invention.

Figure 23 illustrates a front cross-sectional view along lines C-C of FIG. 22 in

passive state.

Figure 24 illustrates a front cross-sectional view along lines C-C of FIG. 22 in compressed state.

Figure 25 illustrates a side cross-sectional view of a bottle embodiment in compressed state with force vectors of flow and external pressures.

Figure 26 illustrates a front view of a bottle embodiment in passive state.

Figure 27 illustrates a partial transparent side perspective view of an alternative bottle embodiment in passive state as applied into a human mouth.

Figure 28 illustrates a side cross-sectional view of a bottle embodiment in passive state.

Figure 28A illustrates a side cross-sectional view of a bottle embodiment in passive state.

Figure 28B illustrates a side cross-sectional view of a bottle embodiment in compressed state.

Figure 29 illustrates a perspective view of a pacifier embodiment of the present invention.

Figure 30 illustrates a perspective exploded view of a pacifier embodiment of the present invention.

Figure 31 illustrates a side view of a pacifier embodiment of the present invention.

Figure 32 illustrates a top view of a pacifier embodiment of the present invention.

Figure 33 illustrates a front view of a pacifier embodiment of the present

invention.

Figure 34 illustrates a cross-sectional side view along lines C-C of FIG. 33.

Figure 35 illustrates a cross-sectional side view along lines B-B of FIG. 32 in passive state.

5 **Figure 36** illustrates a cross-sectional side view along lines B-B of FIG. 33 in compressed state.

Figure 37 illustrates a top view of an alternative pacifier embodiment of the present invention.

Figure 38 illustrates a cross-sectional side view along lines A-A of FIG. 32.

10 **Figure 39** illustrates a cross-sectional side view along lines A-A of FIG. 37 in passive state.

Figure 40 illustrates a cross-sectional side view along lines A-A of FIG. 37 in compressed state.

Figure 41 illustrates a cross-sectional side view along lines A-A of FIG. 32 in
15 passive state.

Figure 42 illustrates a cross-sectional side view along lines A-A of FIG. 32 in compressed state.

Figure 43 illustrates a top view of an alternative bite block of the present invention.

20 **Figure 44** illustrates a top view of an alternative bite block of the present invention.

Figure 45 illustrates a top view of an alternative bite block of the present invention.

Figure 46 illustrates a top view of an alternative bite block of the present invention.

Figure 47 illustrates a top view of an alternative bite block of the present invention.

5 **Figure 48** illustrates a top view of an alternative bite block of the present invention.

Figure 49 illustrates a top view of an alternative bite block of the present invention.

10 **Figure 50** illustrates a side cross-sectional view of a pacifier embodiment of the present invention.

Figure 51 illustrates a cross-sectional view of a pacifier embodiment of the present invention.

Figure 52 illustrates a cross-sectional view of flanges along plane lines F-F in Figure 51.

15 **Figure 53** illustrates a cross-sectional view of flanges along plane lines E-E in Figure 52.

Figure 54 illustrates a cross-sectional side view of a toddler's oral cavity in first position with an embodiment of the present invention applied.

20 **Figure 55** illustrates a cross-sectional side view of a toddler's oral cavity in second position with an embodiment of the present invention applied.

Figure 56 illustrates a cross-sectional side view of a toddler's oral cavity in third position with an embodiment of the present invention applied.

Figure 57 illustrates a top view of an embodiment of the present invention.

Figure 58 illustrates a cross-sectional side view of an embodiment of the present invention.

Figure 59 illustrates a side view of an embodiment of the present invention.

Figure 60 illustrates an exploded perspective view of an embodiment of the present invention.

Figure 61 illustrates a detachable nipple section of an alternative embodiment of the present invention.

Figure 62 illustrates a close-up cross-sectional side view of circle AA of embodiment as shown in Figure 58.

Figure 63 illustrates a frontal view of an embodiment of the present invention in first position.

Figure 64 illustrates a frontal view of an embodiment of the present invention in third position.

Figure 65 illustrates a cross-sectional side view of a newborn's oral cavity in first position with an embodiment of the present invention applied.

Figure 66 illustrates a cross-sectional side view of a newborn's oral cavity in second position with an embodiment of the present invention applied.

Figure 67 illustrates a cross-sectional side view of a newborn's oral cavity in third position with an embodiment of the present invention applied.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With use of embodiments of the present invention, one may provide hygienic and/or orthotropic support to newborns, infants, children, adolescents (or even adults). The present invention may be used to prevent adverse deformation of the tissues and bones associated with the mouth. When used in newborns and infants, the application of orthotropic devices can guide the eruption of teeth and position and orient the bones in an ideal position. Further, via application of rhythmic vibrational signaling, stem cells can be activated, and causing phenotype improvements via epigenetic expression guided via external stimulation of the genotype. Rhythmic vibrational signaling can increase or induce stem cell development in the area of the signal.

Proper orthotropic development may also have multiple other pathways for providing a healthier human, both aesthetically and for health factors. Obstructive sleep apnea affects millions of people of all ages. In children symptoms can range from bed wetting, choking, drooling, coughing, night sweats, behavioral problem, learning disabilities, sluggishness, snoring, teeth grinding, restlessness, attention deficit hyperactivity disorder (ADD or ADHD).

By forming an orthotropically aligned mouth (maxilla and mandible), a root cause of obstructive sleep apnea (OSA) can be minimized, controlled, or even eliminated. With the present invention and embodiments thereof, we may control or prevent these chronic and debilitating diseases.

As can be seen in Figures 13-15, bottle 1 may be equipped with cap 2. Bottle 1 is shown with cap 2. Mouth portion 3 is set thereon, and includes skirt 27 and nipple 5. Cap 2 may be threadedly engaged to screw onto bottle 1. Mouth portion 3, fits onto cap 2, preferably via a

channel lip fastening connection. It is preferable that cap may be removed from bottle via unscrewing, and nipple may be removed from cap, to facilitate cleaning of the bottle and components. Cap is preferably made of a hard plastic, while nipple is preferably made of a softer plastic, silicon, silicone, or other known material for nipples, bottles, and pacifiers. Nipple
5 5 may include air vent 29, preferably set outside area of lips when in use.

With reference to bottle mouth portion 3 in use with a human mouth, Figures 1-2 demonstrate two states of action. Figure 1 demonstrate the mouth portion 3, including skirt 27 and nipple 5 applied to a human mouth prior to application of compressive forces. This is termed the passive state, as with equilibrium forces within and outside the mouth portion, the structure,
10 shape, and orientation remain in passive form. Upper lip 10 and lower lip 11 of the user may fit onto neck 4 as a lip hold along mouth portion of nipple. Major undulations 6 may be provided opposite bottle along neck 4. Major undulations, including both superior major undulation and inferior major undulation 6A and 6B, are preferably set to fit into the maxillary buccal vestibule 16 and mandibular buccal vestibule 17, respectively. Minor undulations 7, fit along/between
15 major undulations (as shown) and join with the main nipple 5 at collar 8. Together, the major and minor undulations form ribs.

When sucking, ribs encourage turbulence of fluid flowing within mouth part, and further prevent vacuum seal against oral surfaces. Ribs further allow expansion of the flanges (undulations) into the collar to fill in portions of the vestibules. Ribs, allow for mechanical
20 cleaning of gums. Micro movements of the ribs may cause a rhythmic vibration, and vibrational signaling, on the oral surfaces to stimulate vascular development, tooth growth, and stem cell growth in the bony membrane and bone development/production. Ribs may form a skirt 27,

while major undulations help define a skirt edge 47, that provides for a bumper to prevent excess pronation of the alveolar ridges to go beyond twenty-degrees from vertical axis 30 (or seventy degrees from horizontal plane 50). Vertical axis 30 and horizontal plane 50 meet at vertex 55, while skirt 27 is intended to roughly rotate along vertex from a more acute angle, as shown below in FIG. 28A, to the wider acute angle, as shown below in FIG. 28B, when exposed to compressive forces to achieve the compressed state (discussed below with reference to FIG. 2). Mandible 15 may be enclosed around nipple for use of bottle. User chin 25 is shown. Nipple 5 may include milk pore 26 at the proximal end of nipple. Milk pore can be one or more apertures in the nipple, dependent on the needed flow rate for feeding in relation to the age/size of infant/user.

As between undulations and nipple, a collar 8 is formed. Collar 8 provides placement for maxillary alveolar ridge and mandibular alveolar ridge, respectively. Maxillary alveolar ridge 12 fits onto superior nipple collar, while mandibular alveolar ridge 13 fits into inferior nipple collar. An inferior lingual ridge 9 may be set as between the undulations and a depressed tongue guide 21. Tongue guide 21 provides for a depression to locate tongue 18. Tongue guide also causes tongue to provide upward force against maxilla, and otherwise exercise and develop habits to strengthen and encourage proper tongue placement when not feeding/using device, and trains the tongue positioning from an early age. Nipple 5 fits into vault 20 of user's mouth.

As seen in Figure 2, the sucking action caused deformation of mouth portion 80 into a compressed state. Force vectors are shown via arrows. Lips 10 and 11 press, or otherwise provide push vector compressive forces against superior and inferior neck 4, respectively (neck 4 providing a lip hold). Upper and lower skirt, 77 and 87, expand, rotate, and move to fill

maxillary and mandibular buccal vestibules, 16 and 17. Maxillary alveolar ridge 12 and mandibular alveolar ridge 13 engage collar 8 to bite down onto mouth portion 3. Tongue 18 further presses upwards and anteriorly into tongue depression guide 21 to press on, or squeeze, nipple 5. When feeding, the mouth serves to suck on nipple in a posterior direction (e.g. as when feeding) to pull nipple. As mouth portion is deformed, nipple 5 extends posteriorly, and skirt 27 extends outwardly.

As can be seen in Figures 3-6, mouth portion 3 in passive (non-compressed) state is shown in Figures 3-4, while in compressed state in Figures 5-6. Air vent 29 is set along neck 4 in proximity to cap 2 (not shown). Major undulations 6 are shown extending at offset extending lengths, with minor undulations 7 set between major undulations 6 and collar 8. As is shown, superior and inferior collars 8 are offset by linear offset 33 which may be as much as 1-3 millimeters to from an orthotropic collar to guide jaw relationships, to optimize positioning as known in natural breast feeding, and facilitate proper orthotropic jaw development. It is contemplated that positioning the superior maxilla, forward by 1-3 millimeters in relation to the inferior mandible, proper alignment of the jaw will be formed.

As can be seen, in Figures 28, 28A and 28B, vertical axis 30 designates a twenty-degree angular offset above 31 and below 32, and horizontal plane 50 designates a seventy-degree offset, as the threshold angle to which the pronating alveolar ridge is abutted and stopped from further pronation. It is contemplated that the angle of the alveolar ridges when engaging the collars will limit the forward pronating angle to twenty degrees as is shown in angle 34. The angle of twenty degrees from vertical, or seventy degrees from horizontal, is preferred as the maximum orthotropic angle for forward extension of the alveolar ridges and teeth as they

emerge. This is in contrast to development of pronate teeth caused by thumbsucking, etc. as is known in the art of pediatric orthodontics. Angles less than twenty degrees are preferable, while an angle between fifteen and twenty degrees is most preferable. Angles beyond twenty degrees would indicate excessive pronate tooth/ridge growth and is prevented by the extending

5 undulations.

Figures 28A-28B demonstrate an alternative embodiment of the present invention. In passive state, as shown in Figure 28A, skirt 27 forms a more acute angle. Additionally, collar 8 is offset at a lower length of approximately 0-1 mm. As mouth portion 3 is exposed to compression forces, skirt 27 expands as minor undulations 7 flatten out to allow major
10 undulations 6 to rotate and extend (so as to fill buccal vestibule). Skirt may be outfitted with surface features. Skirt 27 includes upper skirt 77, which extends to an angle of approximately twenty degrees from vertical, as defined from upper vertex 75 defining an upper vertical axis 76, and lower skirt 87, which extends to an angle of approximately twenty degrees from vertical, as defined from lower vertex 85 defining a lower vertical axis 86.

15 Referring to Figures 26- 27 frenum relief 28 is shown, the device including both superior and inferior frenum reliefs 28. Major undulation 6 are shown as are minor undulation 7, to form ribs 48.

Referring to Figures 4 and 6, nipple 5 may include obstructive sleep apnea (OSA) pads 24. OSA pads 24, both right 24a and left 24b, are adapted to engage the maxilla of the user
20 mouth, and apply small forces to achieve ideal orthotropic growth of maxilla. Internal padding of OSA pads provide for superior and lateral forces when engaging maxilla, and provide treatment for maxillary bone development to reduce risk and effects of obstructive sleep apnea.

OSA pads 24 may include two separate pads, as shown, and milk pore 26 may include one or more holes, or separate openings, to allow for fluid passage from bottle through nipple. OSA pads 24 are preferably thicker pads that allow lateral expansion to aid in orthotropic development of the maxilla and nasal floor. OSA pads 24 press and separate to force expansion of the maxilla. Employing lateral outward pressure on the maxilla, encourages broadening the maxilla, thus causing opening the floor of the nose. This well-developed maxilla and nasal floor provide proper aeration through the nostrils, and increases ventilation through the nose to decrease harmful issues associated with asthma and allergies. Nose breathing helps warm incoming air, filter the air, and mixes nitric oxide (a potent vasodilator) to be received by the alveoli in the lungs. This in turn causes better oxygen absorption and raises oxygen saturation in the blood. Further, with proper stretching/growth of the appropriately widened maxilla through orthotropics, the mandible will be induced to expand to a proper width as well in accordance with widening of upper teeth/ridge in maxilla. Further information on the proper development of the maxilla, oral and nasal structures can be found in article entitled Is it Mental or Dental?

Cranial & Dental Impacts on Total Health by Dr. Raymond Silkman, DDS, published March 30, 2006, published by the Weston A. Price Foundation, attached and incorporate by reference. Major undulations 6 provide for a skirt 24 surrounding nipple. Compressive forces applied (by the mouth) force down on roof of nipple as the infant feed. Compressive forces are also applied to the inferior side by the infant's tongue, and fluid is forced from pore. Superior and lateral forces on nipple/mouth portion are applied to create maxillary orthotropic forces in resistance via OSA pads, and guide better maxillary bone development. The proper bone development reduces the risk of OSA. (Note: passive state shape is shown in broken lines to mark dynamic change in

mouth portion shape.) Additionally, if the OSA pads are used to exert a widening sideways outwardly force that widens the maxilla, one may prevent or treat issues wherein the vault is widened and thereby lowered reducing lift on the vomer and anterior nasal spine, thus preventing rising forces against the ethmoid bone

5 In all embodiments, the OSA pads may be a hard or soft solid, gel or otherwise material as known in the art for oral treatments, such as silicone, rubber, plastic, calcium, silver, zinc, or otherwise. Further, the OSA pads may be self-contained fluid sacs filled with a water, or more viscous fluid to soften the impact on the maxilla, upper palate. The OSA pads may be filled with a fluid that contains non-dissolved particles that provide for minor vibrations as the OSA pad sac
10 is manipulated (or changes shape). Further the OSA pads may be in fluid communication with a fluid filled bladder, such that compression of the bladder forces fluid into the OSA pad sacs.

As can be seen in Figure 3, mouth portion 3 is shown. Air vent 29 is preferably placed on superior side on the anterior edge of mouth portion 3, near where mouth portion meets cap. Minor undulations 7 provide for a zone of undulation that can stretch or otherwise add to
15 turbulence of flowing fluid. Nipple 5 extends posteriorly from orthotropic collar 8, and further include tongue guide 21. Collar 8 includes an offset, whereby skirt superior rib 48a is set forward (or anterior), approximately 1-3 mm relative skirt inferior rib 48b. The offset of the collar and ribs is associated with proper orthognathic alignment of the jaw.

As can be seen in Figure 5, a fluid flow design is shown. Multiple force vectors induce
20 distortion and migration of major undulations 6 to create flaps that fill the maxillary and mandibular buccal vestibules. Air vent 29 is set outside of user lip to allow a one-way valve flow of air into the bottle so as to prevent vacuum within the bottle. Air vent is positioned in a

manner that is shall be preferably on the superior side of nipple, but may be on the inferior side. Both push and pull force vectors impact the mouth portion and nipple. Push forces are provided by the compressive motions, such as lips pursing and alveolar ridges/teeth biting against the upper and lower portions of the device. Further, the tongue pressing upwards causes a push
5 force vector against the nipple, further distorting the shape. Pull vectors are provided by the sucking and vacuum forces that draw fluid from the bottle through the pores and air into the vent. Further, pull vectors cause the nipple to extrude in a posterior direction, and may meet the roof of the mouth vault.

It is preferable that the one-way valve prevents fluid exiting air vent. As the force
10 vectors engage the nipple, the lips purse against collars 8 to squeeze nipples at neck 4. Further, maxillary and mandibular alveolar ridges engage collar 8 to further squeeze nipple. Finally, sucking force induces a pull or vector force towards the throat. Sucking is supported by tongue thrust from tongue 18, preferably at tongue guide 21 on the inferior side of nipple. OSA pads 24 are forced up against the maxilla. Fluid flows out of bottle and through milk pores 26. The path
15 of flow is guided via the shape of the nipple as it is deformed. Undulations 8 extend into vestibules causing a broadening of the nipple. Fluid flows from bottle into undulations and causes turbulence within undulations. This turbulence is preferred to prevent solids from forming, and otherwise as a hygienic cleaning function to prevent buildup of residue, or otherwise stagnant fluid. As the undulations are flushed, fluid continues to flow into nipple, in
20 turbulent fashion until reaching release at milk pore 26. Both the repetitive swallow action and rhythmic vibrational signaling induce stem cell activity.

As can be seen in Figure 6, major undulations 6 form a skirt 41. Nipple 5 includes

tongue depression guide. Here, the mouth portion is shown in full including air vent 29 and channel 39. Channel is set to allow screw cap 2 (not shown) to fit via fastening method over mouth portion. Preferably, cap includes an extending interior flange to fit into channel, while mouth portion is made of a flexible material that can squeeze into cap. OSA pads 24a and 24b are set with a superior cleft 45 set therebetween. OSA pads are preferably of a thicker material, and cleft allows for relative movement of OSA pads to deform flex and bend as the nipple is deformed under pressure. Tongue depression guide 21 is shown along with a single milk pore. The clefting of the internal OSA pads will, upon tongue compression, cause lateral and superior loading of the two maxillary membranous bony plates.

Various shapes of the mouth portion 3 are shown in Figures 7-12. Figures 7-9 show the mouth portion in passive state (when equilibrium forces are set upon system). Skirt 27 include frenum relief 28 to engage with the user's mouth. Here' skirt 27 is closed, and nipple 5 is intruded. Major undulations 6 form skirt 27. Major undulations 6 and minor undulations 7 forms ribs 48. Skirt forms a high angle. Figures 10-12 show the system in compressed form. Nipple 5 is extended (posteriorly) forced by compressive forces and/or sucking vacuum (pull) forces. Skirt 27 flares out as neck 4 is squeezed by lips to provide lateral opening of skirt. Nipple 5 stretches and extrudes. Ribs 48 are also stretched and reach a low angle profile. When ribs and skirt flare out, skirt fills buccal vestibule. Skirt increases in height, narrows (as minor undulations flatten), and turns upright. Skirt 27 also provides a bumper of sort to help guide orthotropic angle of alveolar ridge – preventing excessive pronation.

Mouth portion 3 is shown in isolation for further detail of an embodiment of the present invention in Figures 15-24. Mouth portion 3 includes circumferential features on anterior side,

including edge flange 101 and secondary flange 102 forming channel 105. Channel 105 mates with interior flange in cap (not shown) to provide a flexible, yet water -tight seal when mouth portion applied to cap. Skirt 27 forms with major undulations 6. It is preferred that an even number of major undulations 6, and ribs 48, are formed with a center gap 46 set therebetween on both superior and inferior sides. Nipple 5 includes pore 26, or pores in alternative embodiments. Skirt 27 defines side edges 47, absent of undulations. Nipple 5 includes tongue depression guide 21 on the underside of nipple. Further, OSA pads 24 are set preferably within (as shown, or part of the features of the nipple shell, or less preferably on the exterior surface of nipple shell (not shown)). As shown in Figure 23-24, nipple 5 moves from passive state (Fig. 23) to compressed state (Fig. 24). Tongue guide 21 is forced upwards and further distorts nipple to cause OSA pads 24a and 24b apart. (Superior) cleft 45 allows for mechanical separation and rotation of OSA pads. As shown in Figure 21, fluid flow path is indicated by arrows, fluid entering mouth portion 3, passing through skirt (causing interior flushing/cleaning and causing vibrations) around OSA pad 24 and out pore 26.

Figure 25 further demonstrated the multiple force vectors caused when in use by user's mouth to distort and reshape mouth portion 3 on cap 2. Force vectors induce distortion and migration of skirt (or flaps) and also produce turbulence of flow through mouth portion 3. Pursing of lips 10 and 11 around neck 4 cause compressive force. Alveolar ridges 12 and 13 bite down on collar 8. Tongue 18 provide thrust up against tongue guide 21 and compresses against maxilla vault 20.

Pacifier embodiments of the present invention are shown in Figures 29-42. Pacifier 500 includes superior collar 51 and inferior collar 52. A side wall 53 may separate superior and

inferior collars. Shield 54 is shown as is known in the art to engage with the outer lip of user. Nipple 55 extends to the distal end, and may include a tongue depression 56. Flanges 57 and wings 58 are set on the upper and lower portion of the pacifier. Further, maxillary frenum indentation may be set along the center line to allow for relief for the frenum. As between
5 flanges and wings, a textured surface 150 is placed and intended to make contact with alveolar ridges and otherwise contact vestibules for hygienic, cleaning, and stimulation. Texture provides for cleaning, and stimulation of the gums and alveolar ridges. In a similar manner, in the bottle embodiment, vibrational forces by flow cause undulations to stimulate the vestibules and alveolar ridges. OSA pads 59 may be set on the superior side of nipple, opposite tongue
10 depression 56. Cleft, or ceiling gap 62 is set as between OSA pads 59a and 59b. Frenum relief 28 maybe present on superior and inferior sides. Collar 108 is set on both superior and inferior sides between flanges 57 and wings 58, with sides 151 set on each side. Flanges (and wings) are adapted to bulge and extend when fluid from nipple 55 passes into flanges. As seen in Figure 30, shield 54 is connect to bite block 40 with channel 39 set therein to allow for fluid flow from
15 nipple 55 into flanges 57.

As can be seen in cross-sectional view Figures 34-36, nipple 55 includes OSA pads 59 on right and left side with central ceiling gap 62 set therebetween within cavity 60. Pacifier is preferably hollow, or filled with a fluid, or gas, or otherwise within cavity. As the nipple is under pressure, the nipple collapses forcing fluid in cavity to extend into flanges, and in some
20 embodiments, wings. OSA pads move relative to one another and exert pressure against maxilla. It is preferable that the interior side of OSA pads 59 include a filleted edge with rounded corners.

Nipple 55 includes tongue depression 56. OSA pads 59 fit on superior side of nipple 55

over cavity 60. Flanges 57 and wings 58 are set therein with a bite block 40 separating inferior and superior sides. Bite block includes some aperture or gap to allow fluid to flow from nipple into flanges when pressure is exerted from teeth or alveolar ridges. While prior art has been known to modify the shape or orientation of flanges within a pacifier, prior art is limited to
5 relying solely on pull vectors, or sucking to pull on the device to modify the shape. In embodiments of the present invention, push vectors, such as squeezing of the lips, alveolar ridges, and pressing the tongue against the vault all may be used to cause deformation of the device so as to extend the flanges into the buccal vestibule(s). OSA pads 59 are of a thicker cross-section, as opposed to the central ceiling gap 62.

10 As can be seen in Figures 43-50, portions of pacifier embodiments, such as a bite block of preferred embodiment of the present invention are shown. Shield 54 is set on distal end while nipple extends towards proximal end. Flanges, or skirt 27, are provided and shown for reference. Bite block 40 is preferably made of a flexible yet, preferably somewhat stiffer material than nipple. In some embodiments, same material may be used for both nipple and bite block. An
15 alternative embodiment nipple may be flexible, while bite block may be made of a much harder plastic or other material. Bite block may include right bar 42 and left bar 43 with flow channel set therebetween. In other embodiments, bite block may be made of a single form with an aperture set therein. The aperture may be of any shape, here shown as a square or circle. Furthermore, right and left bars 42 and 43 may be of any shape so long as flow channel remains
20 therebetween.

As can be seen in Figures 51-53, an alternative embodiment of a nipple, or bottle, is shown with articulating extending flanges. In this embodiment, multiple chambers provide for an

articulating extension of the flanges to extend both upward and medially/internally towards the vestibule and alveolar ridge to facilitate and encourage contact against the teeth, and/or ridges. The flanges may expand circumferentially, and the articulating movement causes the flange to approximate the mucosa more intimately. As the first, minor, chamber is filled, overflow into
5 the major chamber will have the effect of better approximating the flange to the angle of the alveolar ridge which inclines posteriorly/inwardly. Further, these extended flanges provide a bumper to prevent excessive pronation of the ridges/teeth beyond twenty-degrees. Bite block 40 is set between chambers and extends into nipple 55. Lips provide a push force vector from both upper and lower surfaces. While tongue provides a further push force vector upwards, forcing
10 fluid anteriorly/forwards from cavity within nipple into chambers to extend flanges. As can be seen in Figure 23, when nipple 55 is compressed, fluid fills into flanges including minor maxillary chamber 72, major maxillary chamber 74, minor mandibular chamber 73, and major mandibular chamber 75. It is contemplated that the minor chambers fill first, extending up and down, while the major chambers fill second, being forced to extend in the distal/internal
15 direction, diagonally both up and down at an angle to cause intimate contact with ridges or ridges/gums (with erupted teeth). Solid portions 71 within flanges are set and do not accept moving fluids but allow for manipulation and change of form, such as balloons.

As can be seen in Figure 52, sides 76 may provide a location wherein central chamber wall 77 meets superior chamber wall 78 and inferior chamber wall 79. Bite block 40 is shown as
20 two separate bars. Frenum indentation is shown as both maxillary 63 and mandibular 64. As fluid is forced out of nipple and into flanges, fluid first enters minor maxillary and mandibular chambers 72 and 73 via fluid flow arrows shown. As the pressure in the minor chambers rises,

fluid is then directed, due to the lower pressure in the major chambers, into the major maxillary and mandibular chambers 74 and 75, causing the flanges to fill the forward buccal vestibules. In this manner, the flanges are articulated in a step-wise fashion so as to force them to extend outward and then distally towards the vaults, or alveolar ridges.

5 The present invention is intended to solve the issue of hygienic problems and provide caries management. The present invention may reduce baby bottle caries. As it is known that 15% more or less of newborns have emerged teeth, caries has become a major issue. The benefits of the present invention are both health and hygiene as well as aesthetics of the development of the maxilla and mouth. By using early guidance of maxilla, one may reverse
10 environmental trends to allow for ideal phenotypic expression of the potential genotype so as to create a healthier and more aesthetic environment. The present invention provides potential dual benefit of hygiene and orthotropics to aid / decrease the risks of OSA.

 The present invention is also directed to an orthognathically corrected pacifier that serves multiple purposes. The device is orthognathically positioned to help nurture the jaws grow into a
15 better alignment. The device may be made up of two separable, or joined parts: an extra-oral casing preferably of hard plastic, (which may include a bite block, the bite block fitting into) an intra-oral bladder, preferably made of an antibacterial material such as silicone. Preferably, the bladder material has shape-memory to revert to a resting position, and is further free of latex, BPA, and phthalate. The bladder may include a nipple and flange(s). Preferably, the size of the
20 device is scalable to allow a variety of sizes (e.g. small, medium, large or neonatal, infant, toddler). Additionally, the relative size and positions of each feature may be modified to accommodate the changing shape of the human mouth as the child grows.

It is preferred that a single chamber is shared between the flange(s)/wing(s) and the nipple. However, a flexible wall or walls may separate the bladder into two or more chambers. The bladder may be filled with a fluid, such as air, gas, liquid, or a more viscous liquid or gel, so as to allow flanges/wings and nipple to modulate in size and shape based on pressure exerted by the position of various muscle movements of the user's oral cavity. Alternatively, the bladder may be filled with a flowing malleable solid or pressure-dependent solid, or may be a solid feature. It is contemplated that the fluid may be a freezable liquid that can be frozen to make the bladder hard (and cold) to provide a soothing effect, such as the relief of painful teething of erupting teeth. Used in its frozen state, as an appliance to soothe and relieve the very painful eruption of primary teeth, such as a teether, etc. freezing fluid solutions may include water with little to no soluble materials (e.g. salt, etc.).

Under standard operating protocols, the invention provides a method for maintaining oral hygiene. As suckling is conducted, the nipple may be compressed by external forces applied by the patient's oral muscles. The suckling motion causes the nipple to compress, and forces transfer of fluid to engorge the flanges. The flanges are therefore expanded. As the flanges engorge, the textured surface or bristles set on the outer surface of the bladder may contact, and move against (or brush), surfaces of the oral cavity. The textured surface and/or bristles may be of a rigid or softer material such as silicone to provide for the mechanical brushing of the ridges.

Additionally, dentifrices, such as emulsified creams or foams or gels, or tinctures, of oils, minerals, natural cleansers, soothing formulae, analgesics, etc. as may be known in the art to provide for improved oral care, may be provided as a dentifrice in, along, and between bristles or ridges. All age appropriate manner of dentifrices known in the art for oral care are contemplated

for use on the textured exterior surface of the bladder. Essential oils (emulsified, diluted, or pure) are preferred, including peppermint, tea tree, lavender, eucalyptus, oregano, palma rosa, orange, lemongrass, geranium, citronella, etc. Alternatively, toothpastes may be used, preferably without fluoride (so as to be safe for use with babies). Currently, many such products are

5 available and useful, such as glycerin, water, silica, algin, calendula extract, prunus amygdalus dulcis oil, clove oil, esculin, limonene, benzocaine, belladonna, xylitol, WINK teething gel, olea europaea oil, salix alba, eugenia caryophyllus flower oil, rebadiana leaf, mentha viridis leaf oil, tocepherol, and many other suitable products as may be known in the art. The dentifrice is applied to the exterior surface of the flanges of the bladder, over and between the textured

10 surface features, such as on and between the bristles.

In order to provide proper orthognathic alignment, the maxillary arch is advanced compared to the mandibular arch by approximately fifteen degrees to promote correct orthognathic growth development. Each arch serves as a flange for placement in front of the teeth and/or gingival ridges.

15 Referring now to Figure 54, cross-section of a toddler's face and oral cavity is shown. Pacifier 10 is placed into the mouth with the shield 12 and mount 11 placed outside the cavity. Upper lip 53 and lower lip 55 fit around shaft 16 to hold pacifier 10 in place. Superior gum flange 30 and inferior flange 32 rest in front of teeth, such as superior incisors 40 and inferior incisors 42, thus facing superior incisor front 41A and inferior incisor front 43A. Teeth bite

20 down on prongs 20, wherein prongs 20 serve as a bite block to prevent the user from biting through pacifier 10 or otherwise compromising fluid flow by occluding bladder 27. Bristles (or textured surfaces) 34 extend along flanges and further along nipple surface (top and bottom).

Nipple 14 is provided to interact with tongue 49 and to be compressed against hard palate 48.

Nipple is comprised of a bulb 18 with shell 26 (preferably silicone or like material) surrounding an inferior bladder 27 filled with air, inert gas, liquid water, viscous fluid, gel, or otherwise.

Bladder extends from nipple into flanges.

5 Moving from first position as shown in Figure 54 to second position as shown in Figure 55, the toddler begins the suckling motion in mouth cavity 50. Tongue 49 depresses against lower side of nipple to force nipple against hard palate 48. As tongue presses against nipple 14, exterior forces provided by the oral musculature provide higher pressure on nipple and bladder, thus forcing the fluid into superior and inferior flanges 30 and 32. Superior and inferior flanges
10 30 and 32 engorge and fill user's vestibule 56 to the front of superior and inferior incisors 40 and 42. As flanges expand, bristles 34 are forced along tooth surface and therefore provide mechanical cleaning of tooth surfaces. Additionally, bristles 34 may extend further on to nipple (not shown) so as to provide cleaning of the rear gum, hard palate, and tongue. In some embodiments, bristles may extend over the entirety of bladder surface.

15 As seen in Figure 56, suckling motion is at maximum. Toddler oral cavity 50 moves into third position. User's tongue provides a higher pressure pressing nipple 14 between tongue 49 and hard palate 48. With this pressure, fluid in the bladder migrates to flanges, and the bladder is forced to change shape to fill both upper and lower vestibules 56 and mate with forward and rear surfaces of teeth 40 and 42. Additionally, bristles on bladder outer surface brush up against the
20 gingival ridges 44 and 46. It is contemplated that in third position, bristled portions of bladder extend over superior gingiva forward surface 45A, superior incisors 40 and front 41A, superior gingiva rear surface 45B of superior gingivae 44, as well as on the lower jaw to cover inferior

incisors 42 in both front and back 43A and 43B, as well as inferior gingivae 46 in front and back 47A and 47B. Tongue 49 depresses against nipple 14 to almost completely evacuate nipple section of the bladder. Interior surfaces of shell 26 may resist sticking to one another when nipple bladder is completely exhausted. It is contemplated that nipple will spring back to memory position and resume the shape of first position once the muscular forces have been removed.

As shown in Figure 57, a top view of the pacifier 10 of an embodiment of the present invention is shown. Handle 13 fits onto mount 11, preferably in a rotatable fashion, through tunnel 15. A shield 12 is provided to cover the front of the lips. Superior gum flange 30 is provided to initially set in front of the superior incisors. Teeth bite down onto bristles 34 at bristled section 35 against bite block 38 shown as an interior portion of the product that would not be viewable unless transparent materials are used. Nipple 14 extends with bulb 18 as is known in the art.

As shown in Figures 58-59, side views of the apparatus demonstrate further aspects of the present invention. Again, pacifier 10 includes handle 13 mounted onto mount 11 through tunnel 15. Shield 12 is not intended for insertion into the oral cavity. Bite block 38 is formed to prevent teeth or gums from biting down on through or otherwise impeding movement of fluid within bladder. Shield and exterior portions of the pacifier mate with the nipple bladder via shaft 16. Superior gum flange 30 is set slightly forward of inferior gum flange 32 by approximately fifteen degrees to provide for proper orthognathic positioning of the jaw. The offset may be as little as zero to five degrees, or as much as forty-five degrees, depending mostly on the thickness of the nipple and/or bite block, and the age/development of the child user.

Bristles 34 extend onto flanges and onto nipple 14. Fluid 46 is shown within shell 26 as may be forced into flanges and otherwise to change the shape of nipple. It is preferred that the shape and dimensions of the flanges accommodate orthognathic placement of the alveolar ridges.

For illustrative and general relative proportional understanding, a model size is hereby
5 discussed. It is contemplated that in a preferred model size, the superior flanges will be set approximately 3mm anterior of similarly shaped inferior flanges. Flanges may be set roughly transversely extending from the nipple bulb approximately 3 mm, with the longitudinal bulb approximately 4 cm long. The textured area, including the bristles or fingers, may be as extend
10 longitudinally), to cover the teeth and reach the gums. The lip shield may include a transverse diameter of as much as 8 cm. The shield may be as thin as 5 mm, and may be the bite block 5mm high. The prongs of the bite block may be set apart 8mm (infant), 1 cm (toddler), and 1.5 cm (older child) to create the fluid channel.

As can be seen in Figures 58-59, the shape of the nipple 14 may not be completely round
15 and symmetrical, but in some embodiments may include a differing upper and lower section. It is helpful to have a shaped flange to provide for proper alignment of upper and lower section to ensure that the orthognathic nature of the present invention is properly aligned with the front jaw forward and lower jaw rear by approximately 3mm, ranging widely 1mm to 7mm, or ranging narrowly 2.5mm to 4mm.

20 Bladder shell may include one or more wings, or a circumferential wing (as shown in Figure 6) along outer surface of shell. Upper wing 62 and lower wing 64 are preferably placed posterior of superior flange 30 and inferior flange 32, respectively, to form superior valley 66

and inferior valley 68, respectively. Superior valley 66 provides for a space to allow superior alveolar ridge to set in proper place along bladder surface. Similarly, inferior valley 68 provides for a space to allow inferior alveolar ridge to set in proper place along bladder surface. In this way, proper positioning of the ridges, and the jaw can be assured. Furthermore, wings may be
5 hollowed (not shown) and share the common chamber as the flanges shown, wherein the wings may also expand to fill the vestibule upon sucking. Otherwise, the wings are meant to be smaller (or extend less) than the flanges so that when bristle surface 35 of bladder 27 extends into vestibule, the wings do not interfere.

As seen in Figures 60-61, in one embodiment, the present invention includes two
10 separable pieces. Two independent pieces may be attached to provide a functional unit. A first extra-oral piece, or base portion 1, and a second intra-oral nipple portion 2. The nipple portion may form a bladder with an open end to be affixed to the base portion to provide a seal. Alternatively, the nipple portion may form a complete continuous shell to provide a sealed bladder, the nipple portion including one or more cavity(ies) 80 (or recess on flat facing mating
15 surface) for the emplacement of the bite block.

The first piece, or base portion 1, includes handle 13, mount 11, shield 12, and prongs 20 of bite block 38. Base portion 1 may include a hollow portion (filled with air), such as shaft and lip shield, for comfort. Prongs 20 form the bite block 38 and have channel 21 set therebetween. Channel allows for bladder to fit over prongs and allow movement of fluids into flanges. In this
20 way, when the child bites down on the device, a channel is formed to allow fluid to flow anteriorly within bladder from the nipple into the flanges. Flanges may include upper indent 57 and lower indent (not shown) centrally positioned on flange ridge to accommodate a frenulum.

The nipple portion 2 includes a bladder 27 that is formed by shell 26. Bladder provides both nipple 14 and flanges 30 and 32. It is contemplated that the device may include a nipple portion that is completely sealed. In an alternative embodiment, when base portion 1 and nipple portion 2 are combined and mated, the nipple portion 2 will be filled with the fluid and sealed against base portion 1 thereby enclosing the fluid in the reservoir.

Figure 62 demonstrates a close-up of lines A-A' in Figure 58. As can be seen, bladder 27 is filled with a viscous fluid 36. Shell 26 includes a bristle section 35 with bristles 34. Bristles may be of a variety of shapes, including sharp and triangular ridges, nubs, tubular, conical, hemispherical bumps, rounded ridges, pyramids, etc. as may be known in the art to provide for friction against an interior surface of an oral cavity. Such bristles or bristle section makes up surface features useful for mechanical brushing of oral tissues. Between various sizes of the product(s), bristles may be shorter for neonates without teeth, and longer for older children with erupted teeth. Superior gum flange 30 includes a filled portion 31 that is filled with fluid 36 shared between bladder in nipple and bladder in flanges. Bite block 38 is provided by prong 20.

As can be seen in Figures 63-64, the nipple bulb 18, shield 12, and flanges 30 and 32 are shown. In this embodiment, superior and inferior flanges form an entire circumferential fill around shaft 16. In an alternative embodiment, superior and inferior flanges are separable. Bristle section 35 is shown. In Figure 63, first position, bulb is filled with fluid. Moving to third position as shown in Figure 64, nipple bulb 18 is depressed and compressed providing an extension of bristles and bristle section towards flanges 30 and 32. As can be seen, superior gum flange 30 and inferior gum flange 32 include upper indent 57 and lower indent 58 to accommodate for superior labial frenulum and inferior labial frenulum, respectively.

As can be seen in Figures 65-67 a new born in first, second, and third position, respectively is shown. Pacifier 10 is placed partially into oral cavity 50, with shield 12, or lip guard, set against upper lip 53 and lower lip 55. Newborn lips are known to be shorter than developed lips and enlarge as the child grows. The incisors, having yet to emerge, are confined within superior ridge 140 and inferior ridge 142. Bristles 34 can be set against the ridges 140 and 142 to provide for massaging or otherwise frictional cleaning of the gingival surface along the ridges. Similarly, as the suckling commences, the mouth mimics a set of feeding postures. As the tongue 49 depresses nipple 14 against hard palate 48, fluid 36 is forced in bladder 27 from bulb 18 into flange filled portions 31 and 33 of the superior 30 and inferior 32 flanges. The vestibules 56 are thus filled with the flanges to provide for frictional cleaning of oral surfaces.

CLAIM:

1. An oral pacification device adapted to be at least partially inserted into the oral cavity, said device comprising:

a. a bladder comprising an exterior shell and a fluid-filled chamber, the bladder forming a nipple at a posterior end and an at least first flange along an anterior end;

b. said chamber extending into said nipple and said at least first flange, a nipple interior in fluid communication with a flange interior;

c. wherein said bladder adapted to revert to a resting shape, said bladder forming a compressed state when said nipple is exposed to external compression forces wherein fluid flows from said nipple to said at least first flange, said compressed state comprising an extended at least first flange.

2. The oral pacification device as set forth in Claim 1 wherein at least a portion of said shell adapted to distort with flowing fluid from said nipple to said at least one flange when bladder transforms from resting shape to compressed state.

3. The oral pacification device as set forth in Claim 1 wherein said extended at least first flange comprises an articulating dual chamber expansion system, said expansion system comprising a superior minor chamber, and a superior major chamber.

4. The oral pacification device as set forth in Claim 3 wherein said superior minor chamber exhibits an outwards and posterior force on said superior major chamber.

5. The oral pacification device as set forth in Claim 1 comprising a superior frenum indentation within said at least first flange.

5 6. The oral pacification device as set forth in Claim 1 further comprising a bite block set with said bladder, said bite block providing a passage allowing fluid communication as between said nipple and said flange.

7. The oral pacification device as set forth in Claim 1 wherein said nipple comprises
10 at least one OSA pad positioned along a superior surface of said nipple.

8. The oral pacification device as set forth in Claim 7 wherein said nipple further comprises a second OSA pad positioned along a left superior surface of said nipple, and wherein said at least one OSA pad positioned along a right superior surface of said nipple.

15 9. The oral pacification device as set forth in Claim 8 wherein said nipple comprises a superior cleft set between said at least one OSA pad and said second OSA pad.

10. An oral device adapted to be at least partially inserted into the oral cavity, said
20 device comprising:

- a. a nipple set along a posterior end of said oral device;
- b. a tongue guide depression set along an inferior surface of said nipple;

c. a skirt coupled anterior relative said nipple, said skirt comprising at least one superior major undulation, said at least one superior major undulation adapted to expand or rotate when said nipple is exposed to external pressures.

5 11. The oral device as set forth in Claim 10 further comprising at least one pore set along a posterior end of said nipple.

12. The oral device as set forth in Claim 10 wherein said nipple comprises at least one OSA pad along a superior surface of said nipple.

10

13. The oral device as set forth in Claim 10 wherein said nipple comprises at least a second OSA pad along a superior surface of said nipple, said at least one OSA pad and said at least a second OSA pad coupled via a superior cleft along a central superior section of said nipple.

15

14. The oral device as set forth in Claim 10 further comprising a minor undulation set inferior said superior undulation along said skirt, said major undulation and said minor undulation forming a rib.

20 15. The oral device as set forth in Claim 10 wherein said nipple and skirt comprises a mouth portion, and said mount portion comprising an anterior end, said mouth portion anterior end coupled to a cap.

16. The oral device as set forth in Claim 15 further comprising a bottle coupled to a cap anterior end.

5 17. The oral device as set forth in Claim 10 further comprising a neck set anterior said skirt, said neck comprising an air vent.

18. The oral device as set forth in Claim 10 wherein said undulation when expanded or rotated forms an approximate maximum twenty-degree angle relative a vertical axis, or
10 seventy-degree angle relative a horizontal plane, bisecting said device.

19. The oral device as set forth in Claim 10 said skirt further comprising an inferior undulation, said inferior undulation offset at least one millimeter posterior relative said at least one superior undulation.

15 20. The oral device as set forth in Claim 10 said device comprising a central plane bisecting said device along a right and left section, said skirt further comprising a second superior undulation, said at least one undulation set on the right section and said second superior undulation set on the left section, wherein said central plane is devoid of an undulation.

20 21. The oral device as set forth in Claim 10 further comprising a frenum relief along a superior edge of said skirt.

22. A method for feeding from a bottle with a mouth portion set along an open end of the bottle, said method comprising:

- a. at least partially inserting a passive state nipple into the oral cavity;
- b. closing lips around a neck of the mouth portion;
- c. pressing a tongue against a guide along an inferior side of the nipple;
- d. biting down with maxillary and mandibular alveolar ridges onto a collar, the collar providing a separation between a skirt and a nipple;
- e. setting the skirt at least partially into the buccal vestibule.
- f. pressing at least one of the lips, the alveolar ridges, and/or the tongue against the mouth portion;
- g. distorting the mouth portion to cause the skirt to open; and
- h. drawing fluid from bottle out of pore in nipple.

23. The method as set forth in Claim 22 further comprising the step of allowing air to enter the bottle through an air vent along the neck of the mouth portion to compensate for vacuum pressures in bottle related to said step of drawing.

24. The method as set forth in Claim 22 wherein the open skirt presses against anterior sides of at least the maxillary alveolar ridge.

25. The method as set forth in Claim 24 wherein said open skirt is extended to open approximately twenty degrees from vertical.

26. The method as set forth in Claim 22 further comprising the step of extending the nipple posteriorly during said step of distorting.

5 27. The method as set forth in Claim 22 wherein a relative offset is formed as between the anterior-posterior location of the vertices of each of the superior and inferior skirts.

28. The method as set forth in Claim 27 further comprising the step of extending the offset as between an upper skirt and a lower skirt during said step of distorting.

10 29. The method as set forth in Claim 22 further comprising the step of causing rhythmic vibrational signaling through the skirt to at least one alveolar ridge.

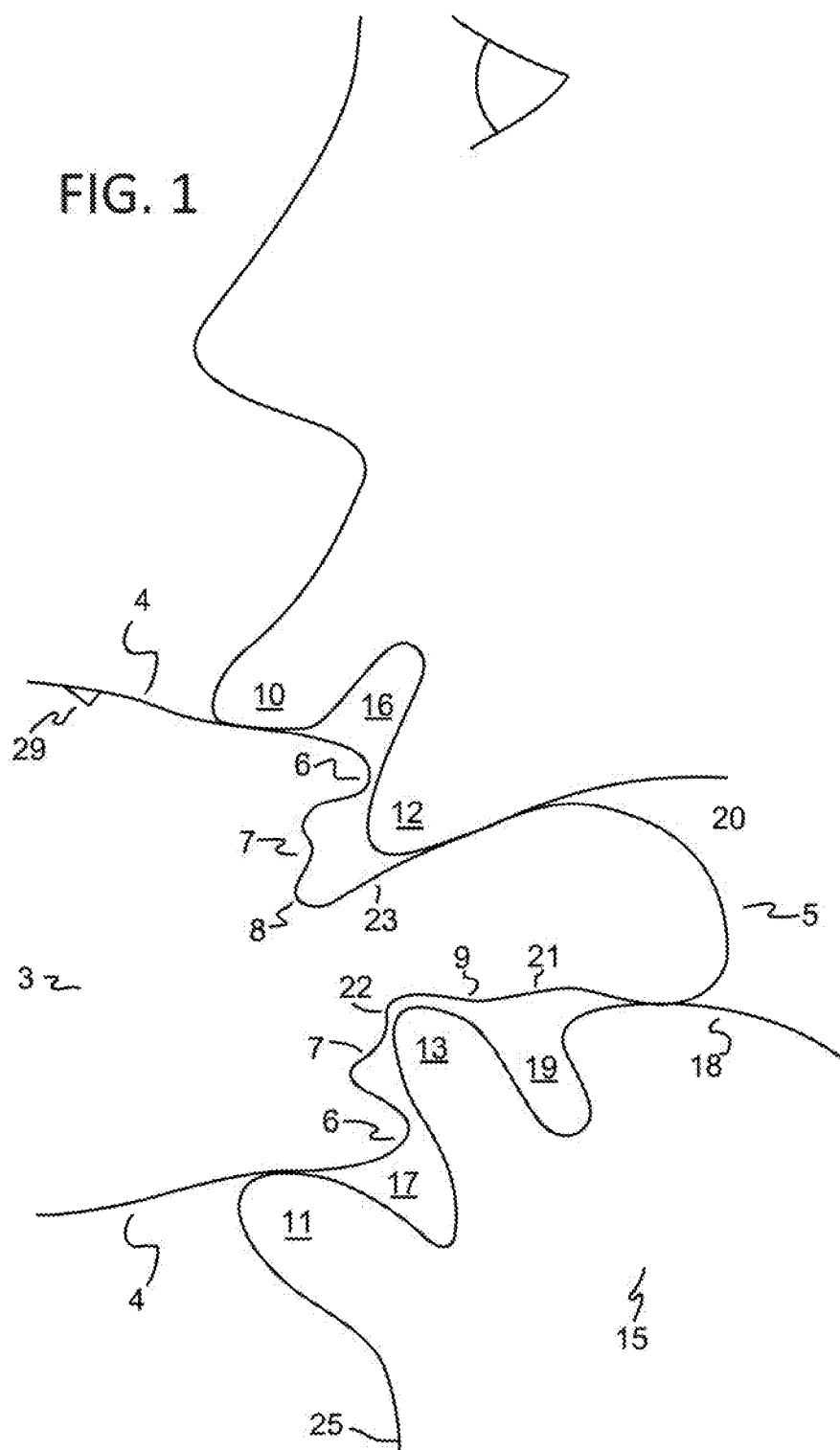
30. The method as set forth in Claim 22 further comprising the step of pressing OSA
15 pads on a superior side of the nipple against a maxillary surface.

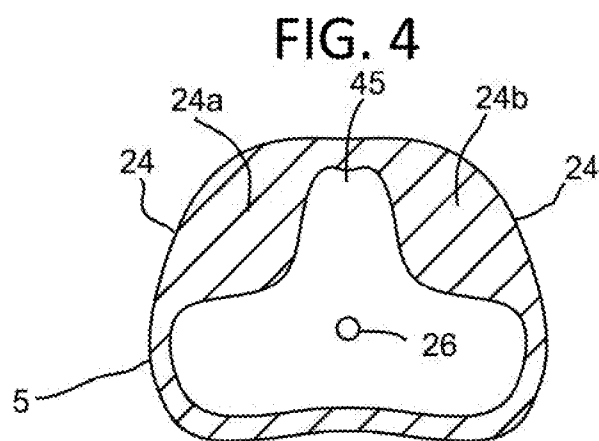
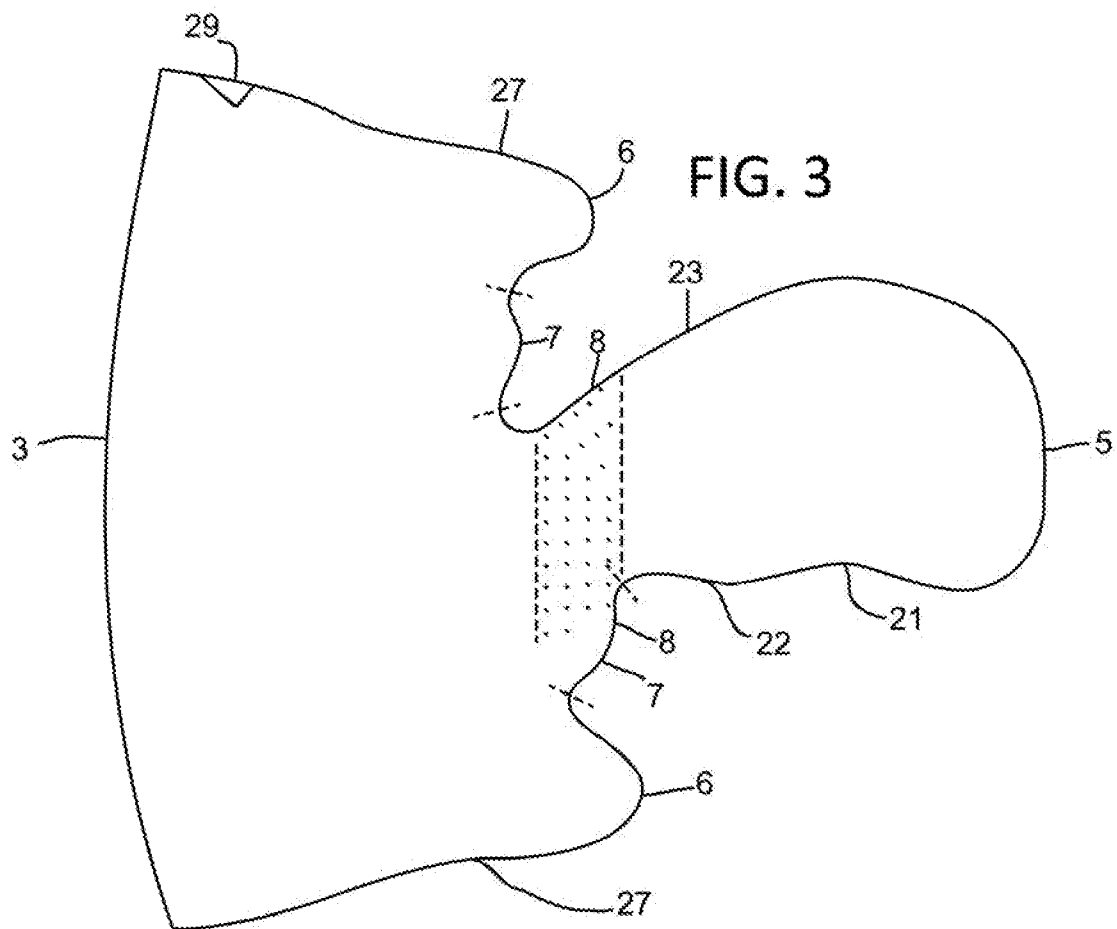
31. An oral device comprising OSA pads adapted to engage with the upper palate.

32. A method of engaging with the maxilla or upper palate to effect muscular-skeletal
20 treatment.

33. An oral device comprising features adapted to engage the alveolar ridge.

FIG. 1





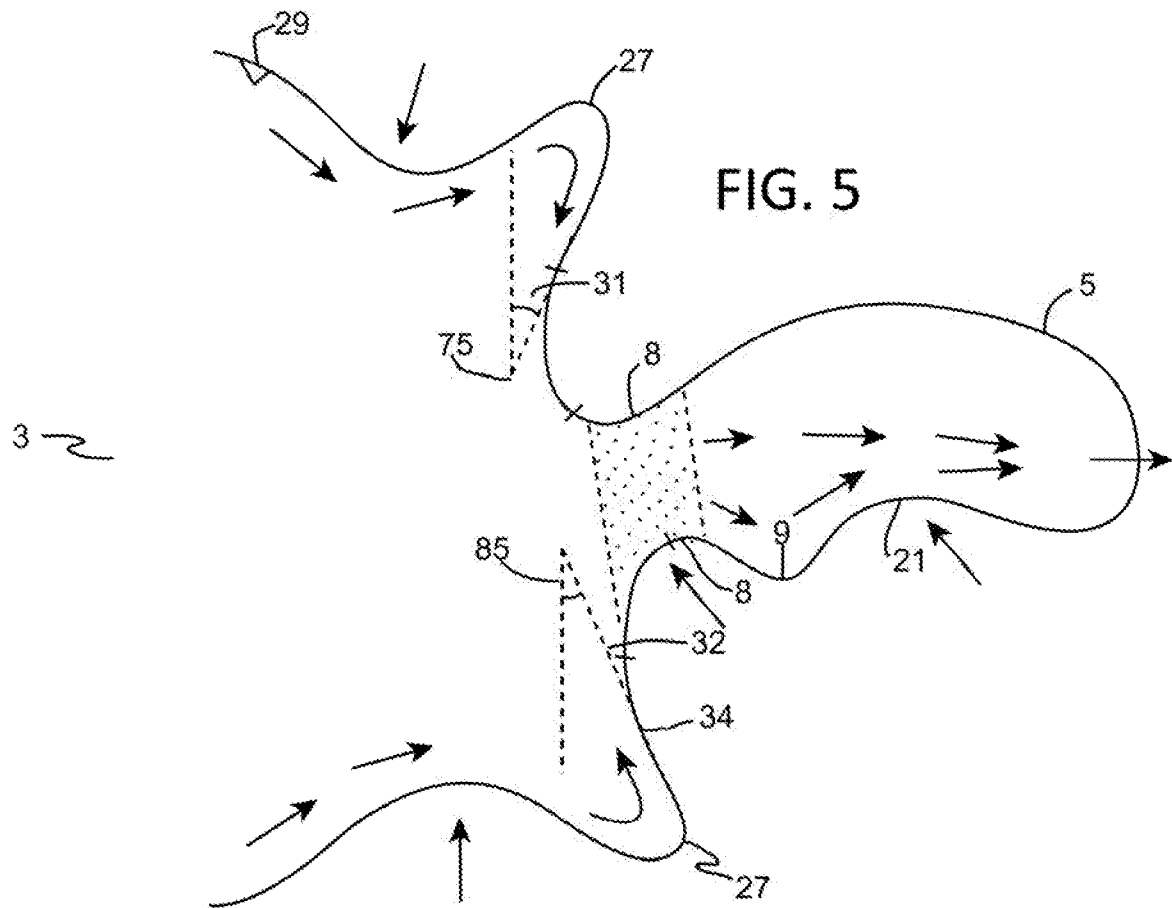


FIG. 6

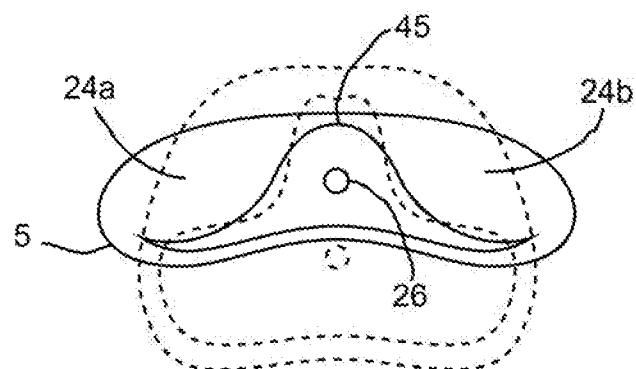


FIG. 7

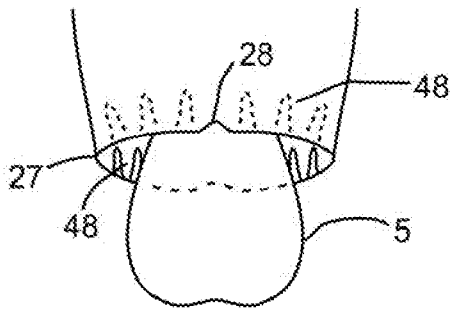


FIG. 10

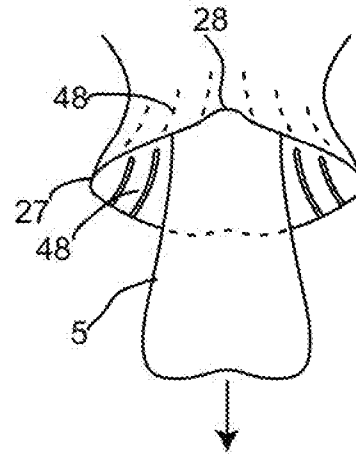


FIG. 8

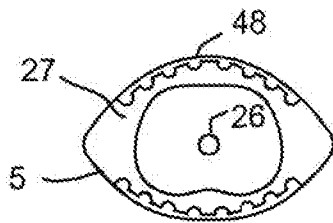


FIG. 11

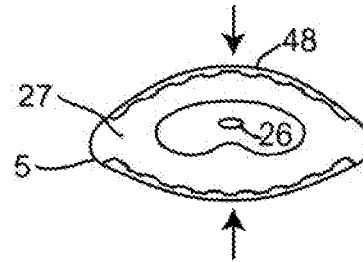


FIG. 9

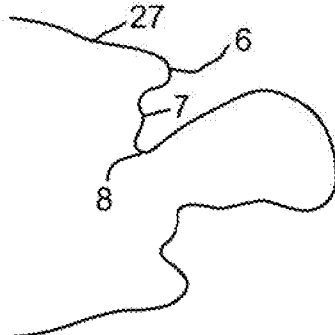


FIG. 12

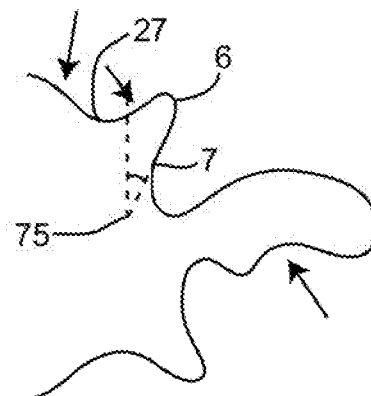
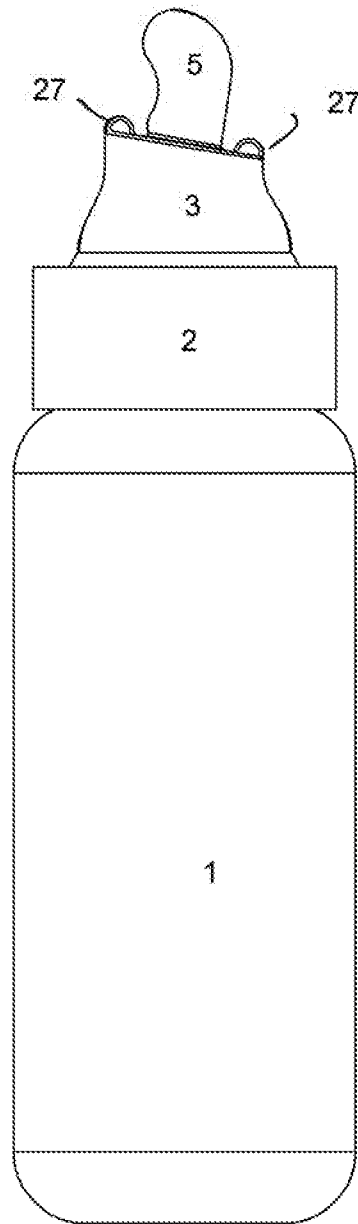


FIG. 13



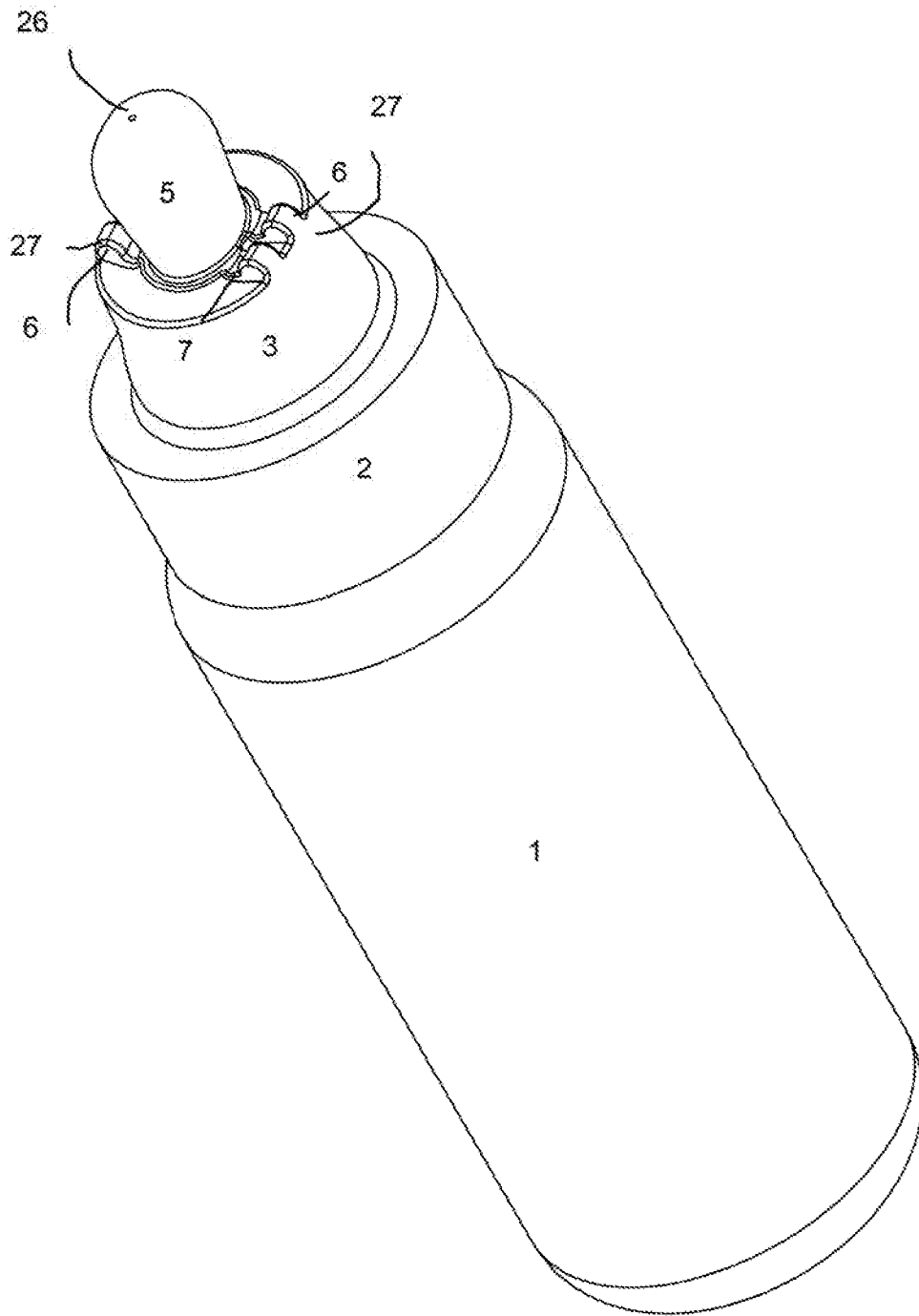


FIG. 14

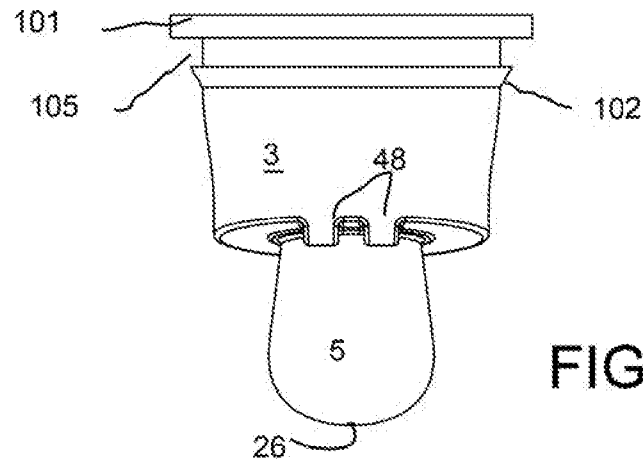


FIG. 15

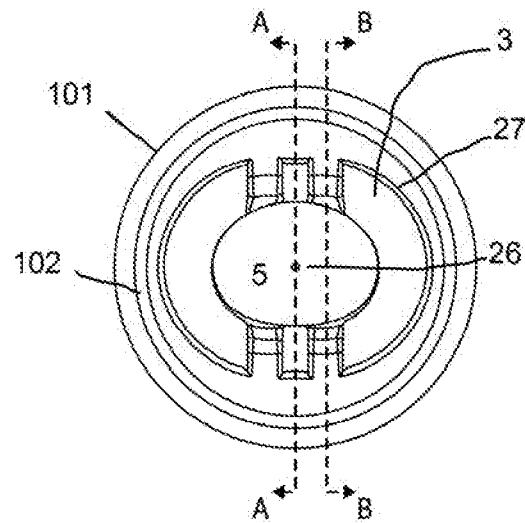


FIG. 16

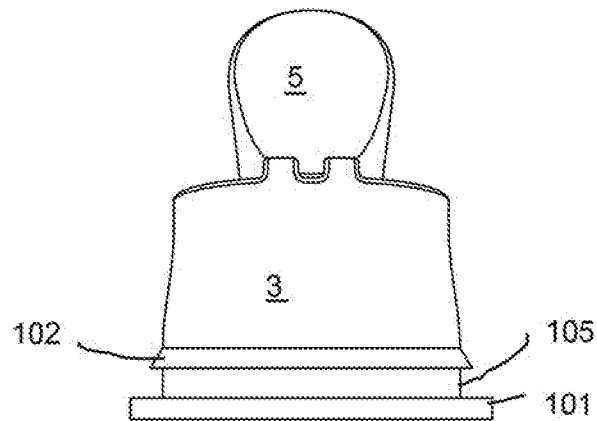


FIG. 17

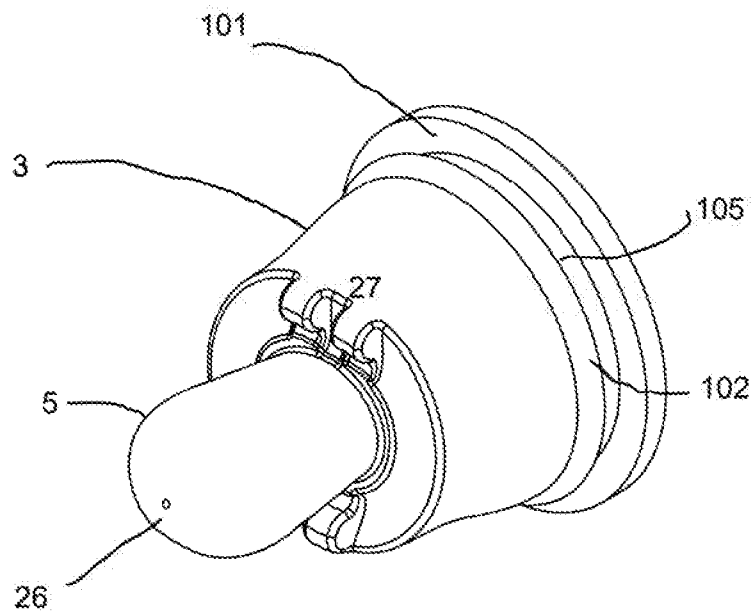


FIG. 18

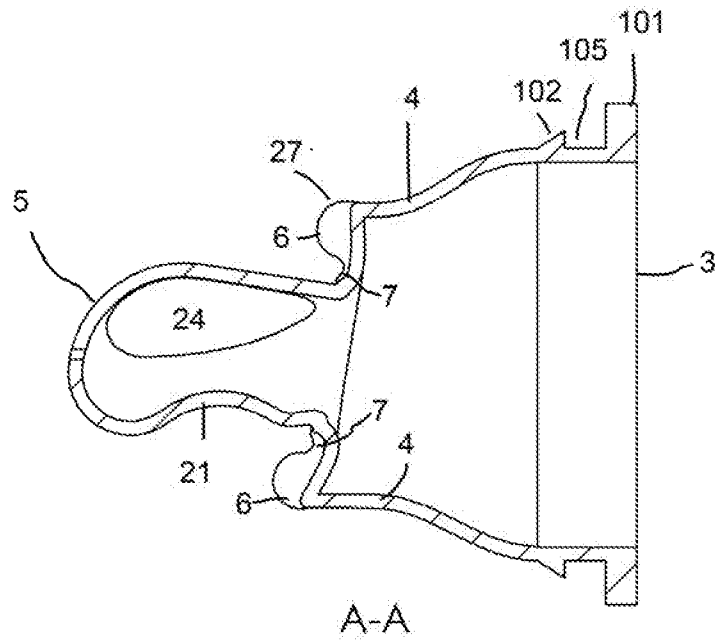


FIG. 19

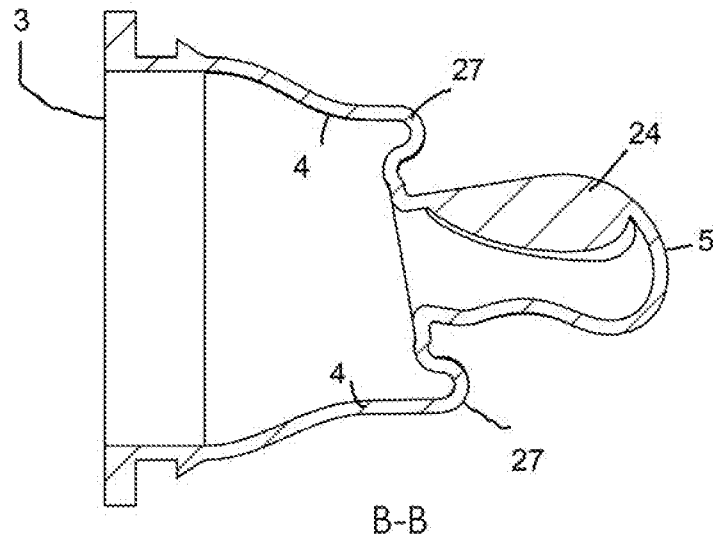


FIG. 20

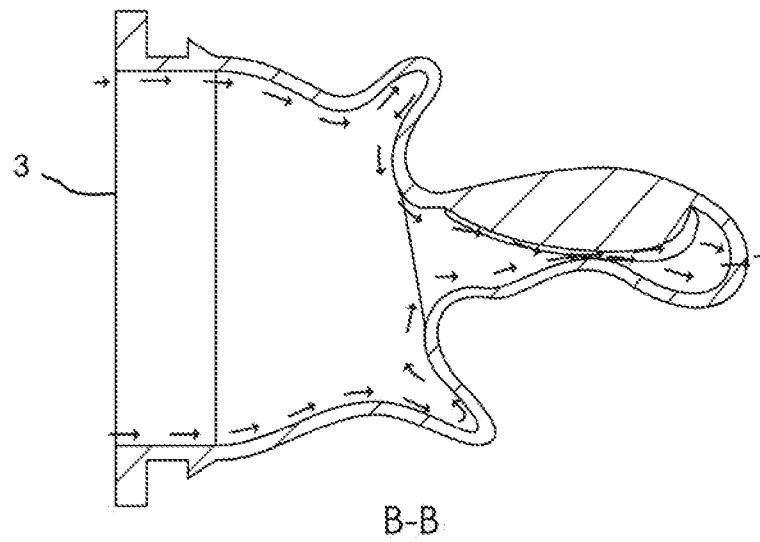


FIG. 21

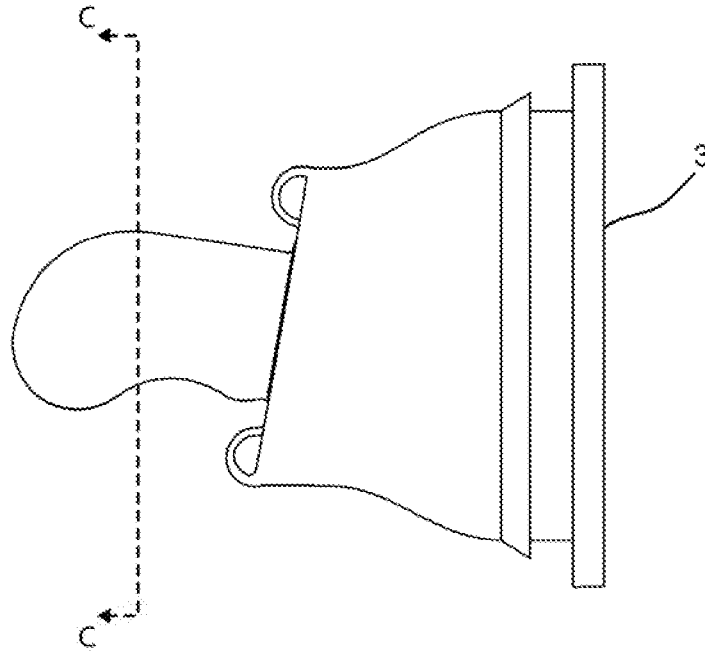
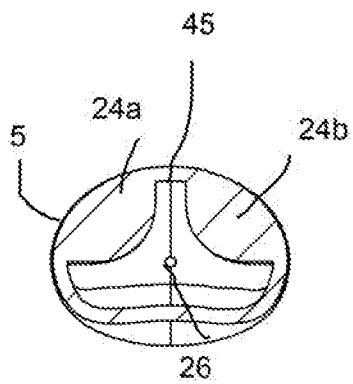
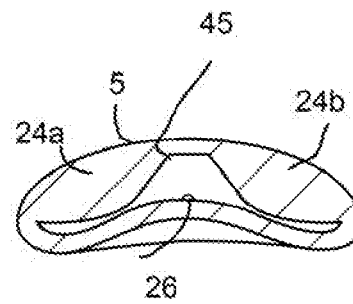


FIG. 22



C-C

FIG. 23



C-C

FIG. 24

FIG. 25

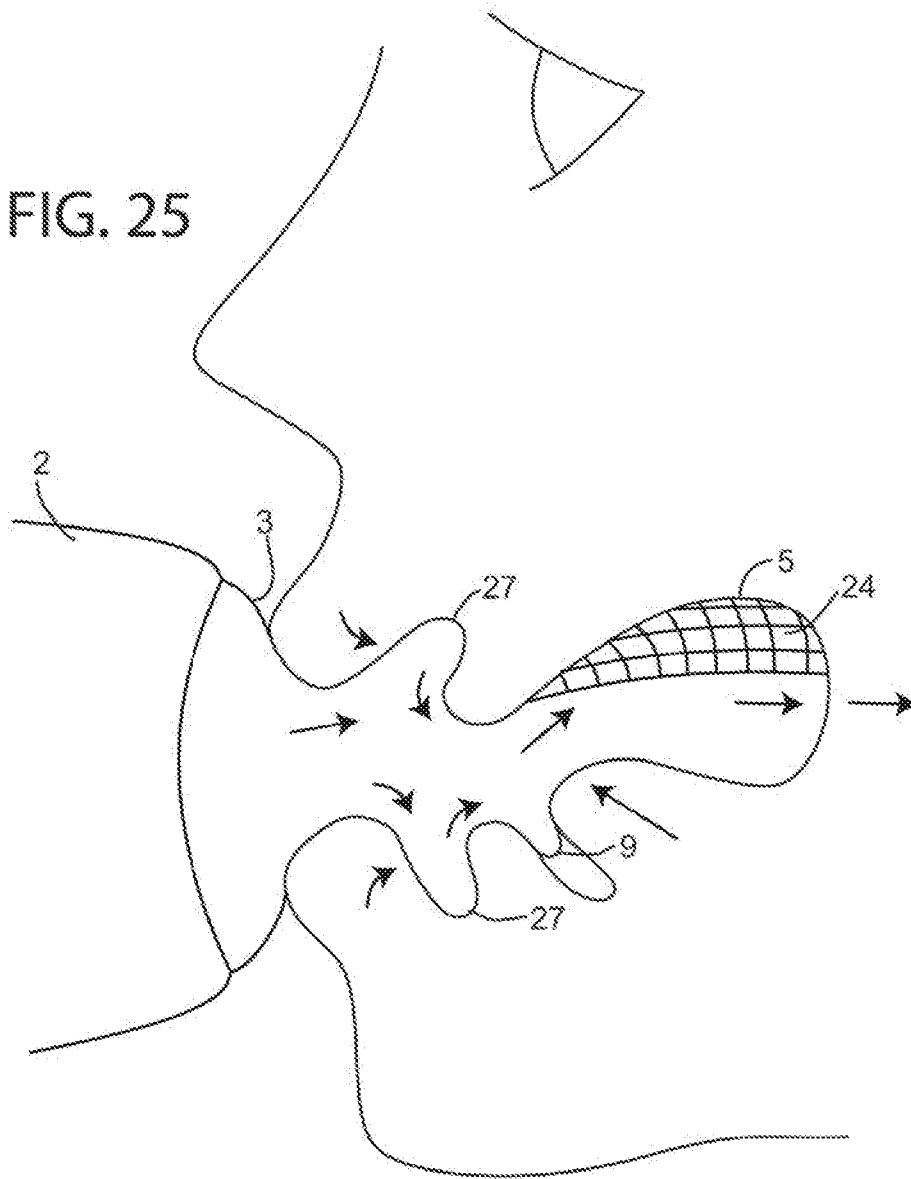


FIG. 26

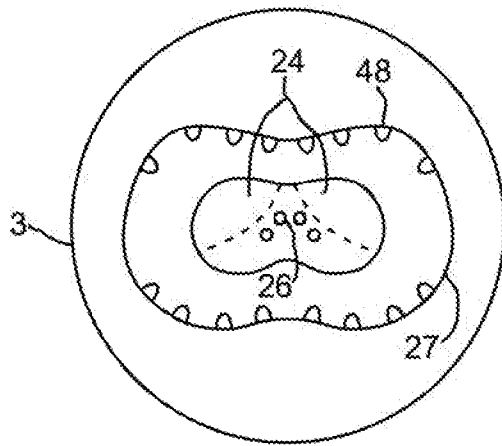


FIG. 27

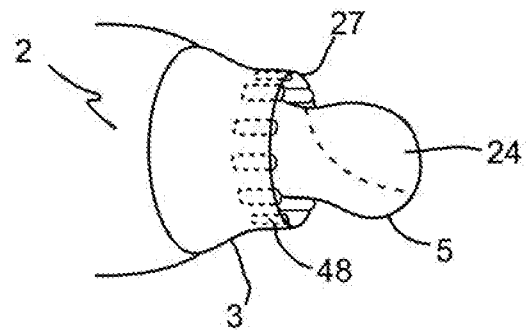


FIG. 28

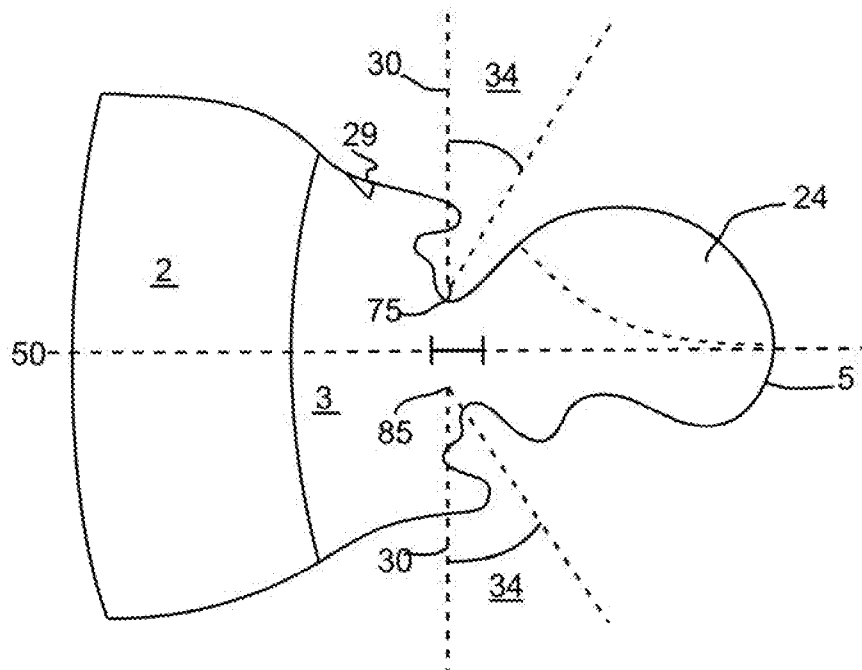


FIG. 28 A

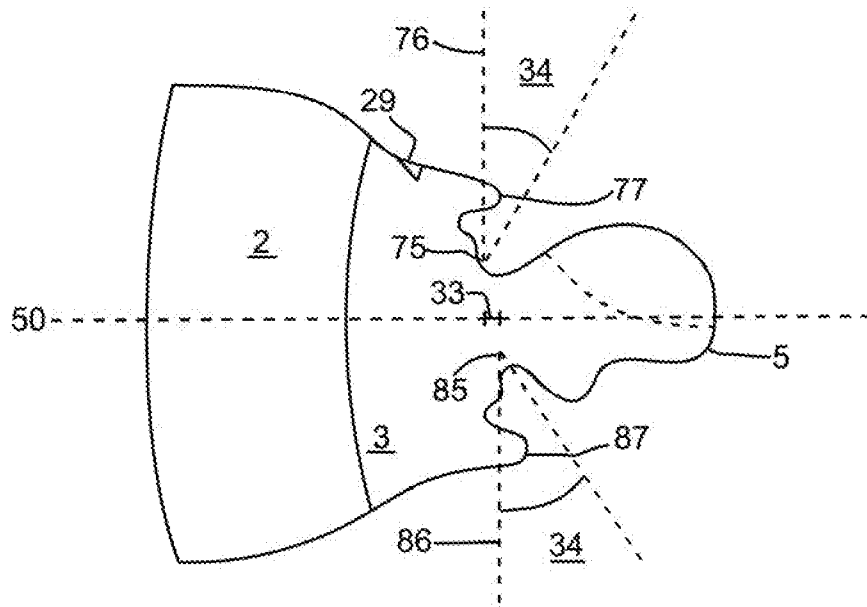
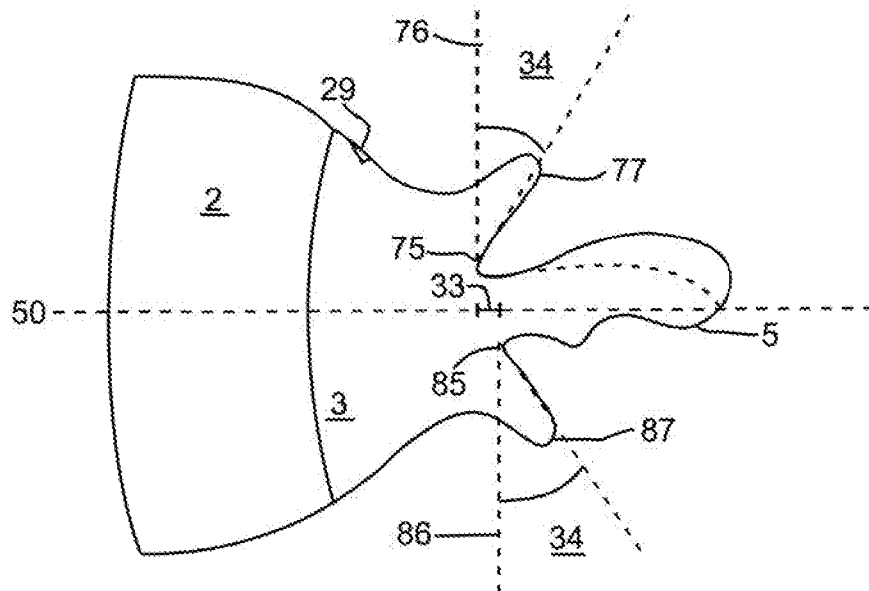


FIG. 28 B



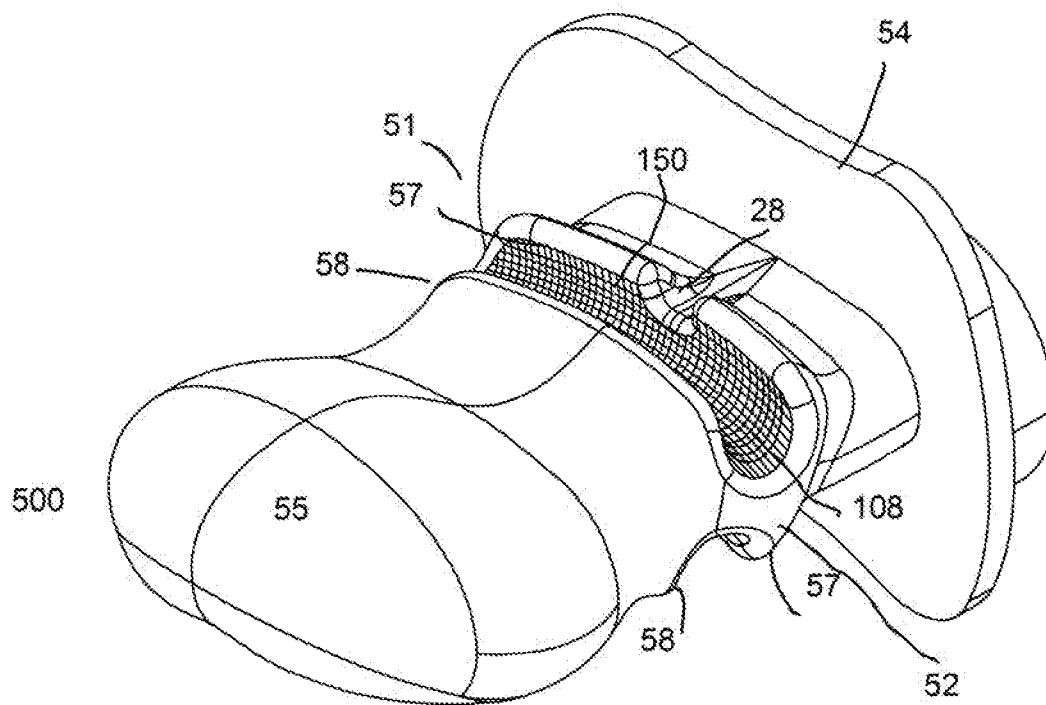


FIG. 29

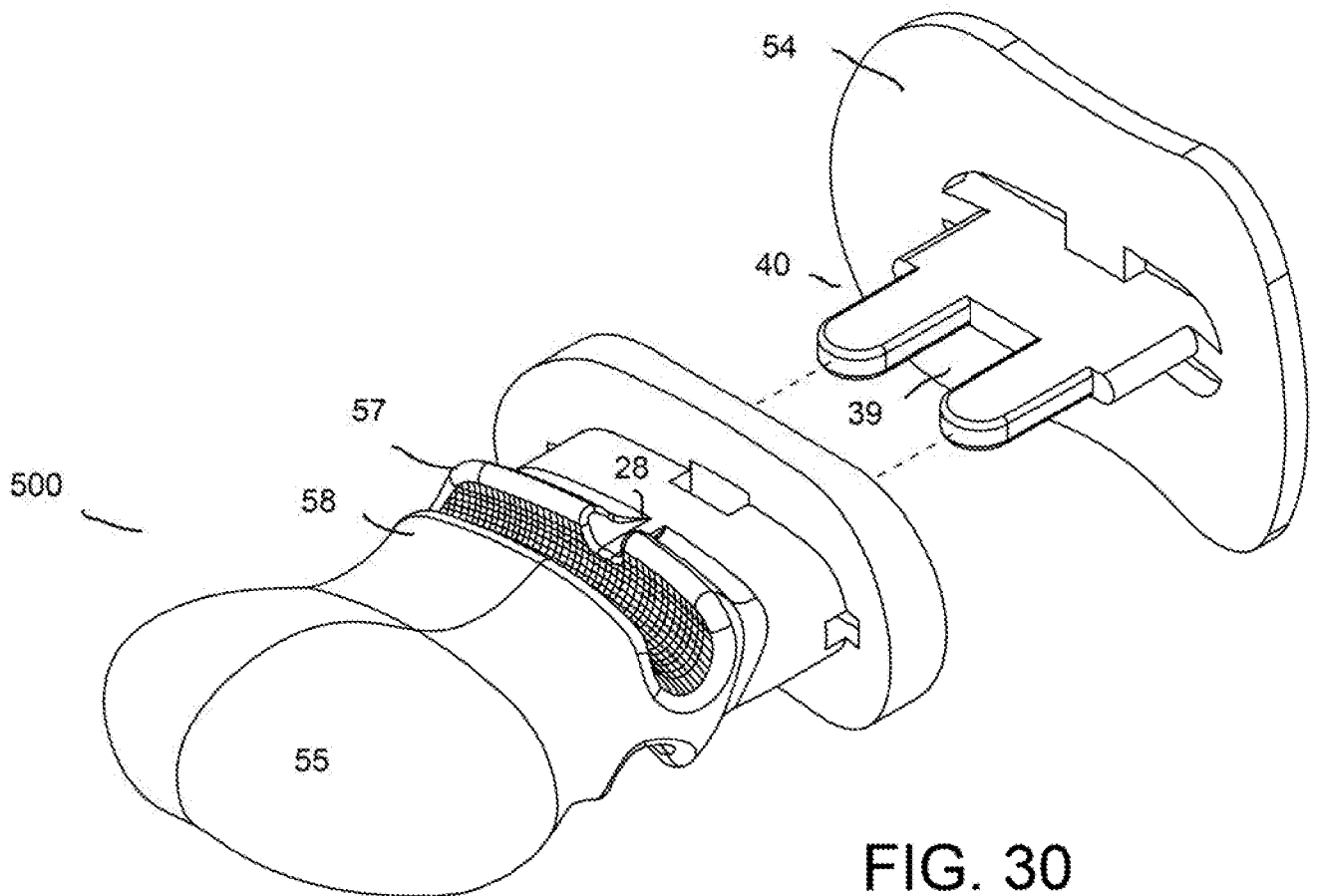


FIG. 30

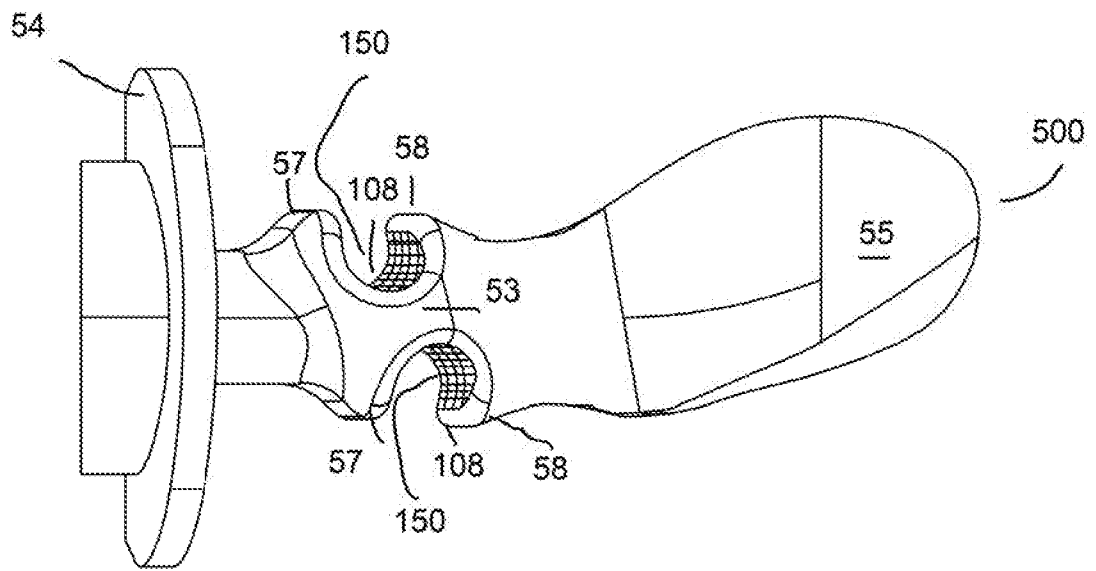


FIG. 31

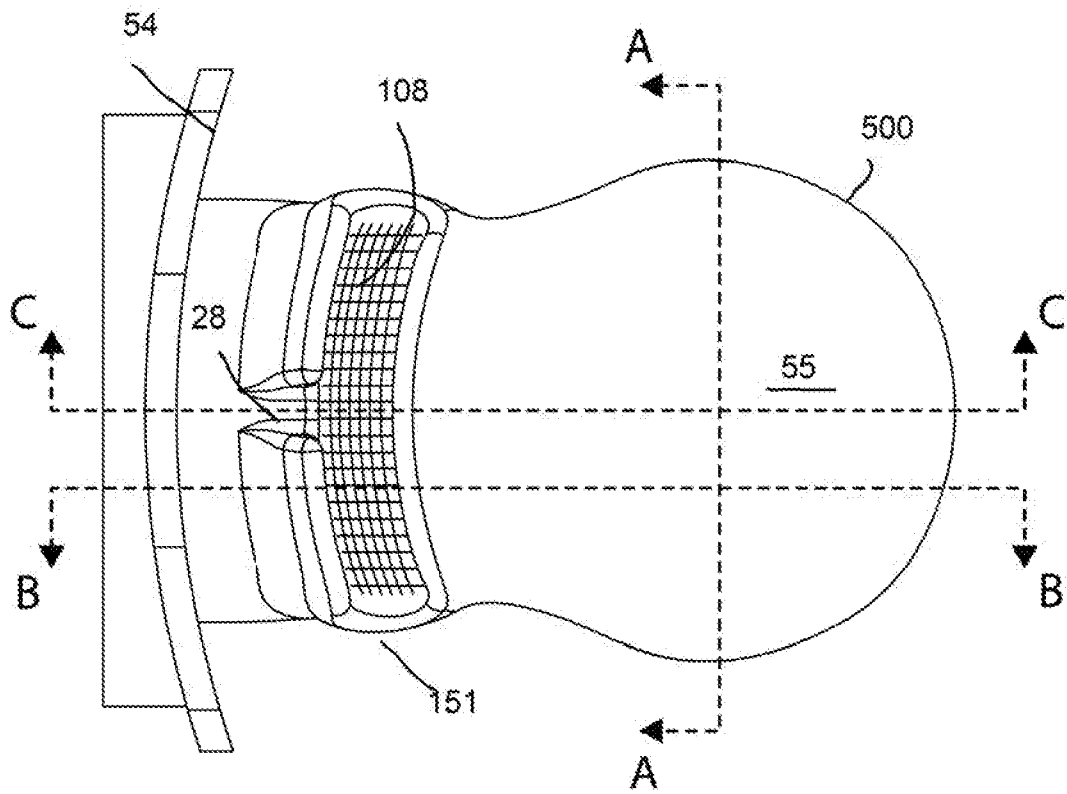


FIG. 32

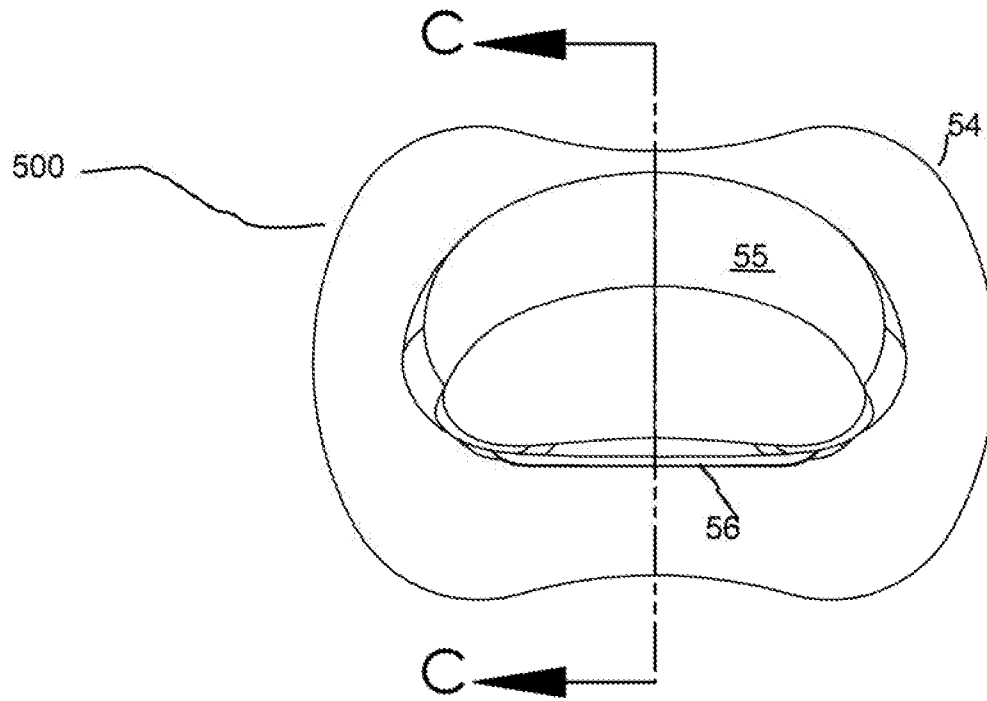


FIG. 33

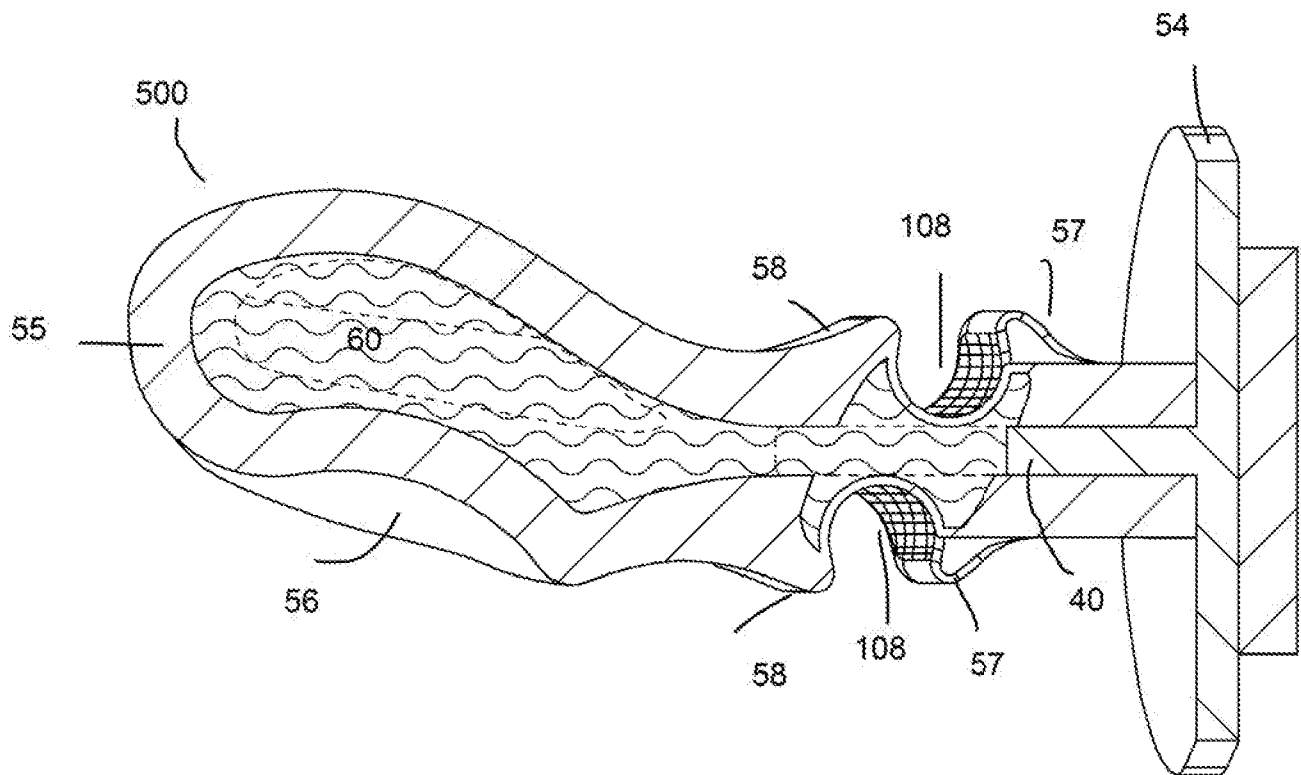


FIG. 34

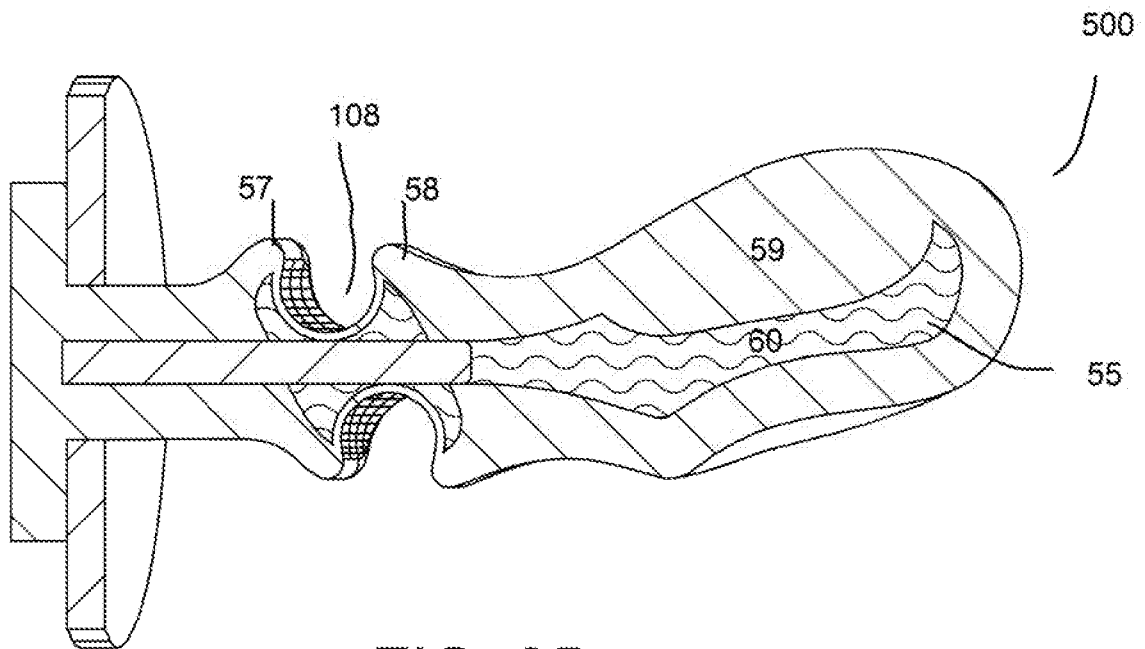


FIG. 35

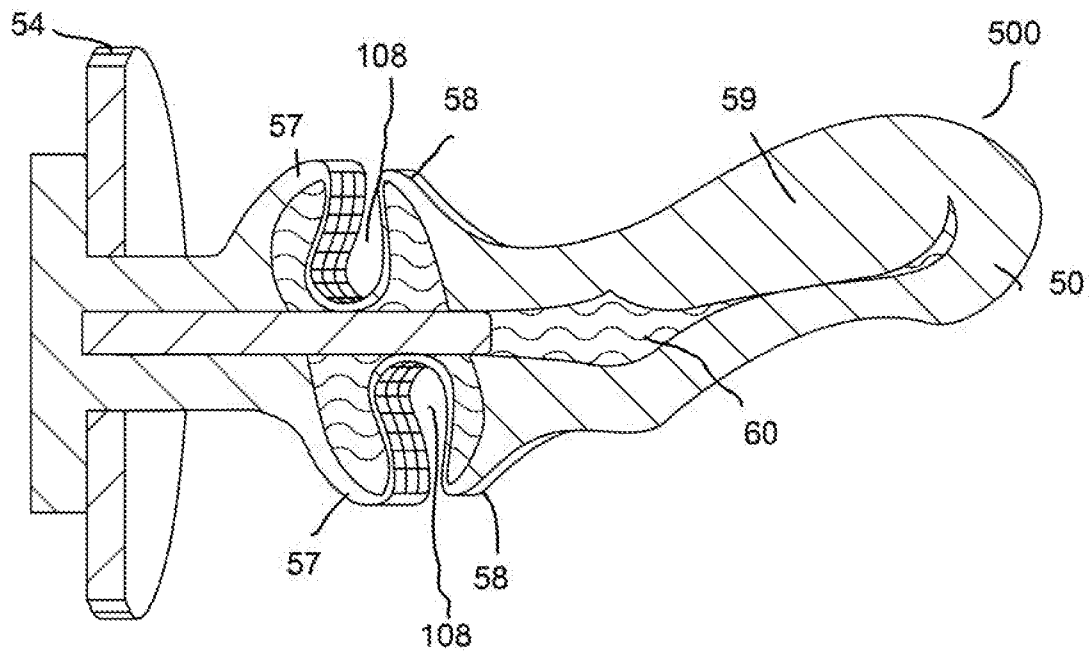


FIG. 36

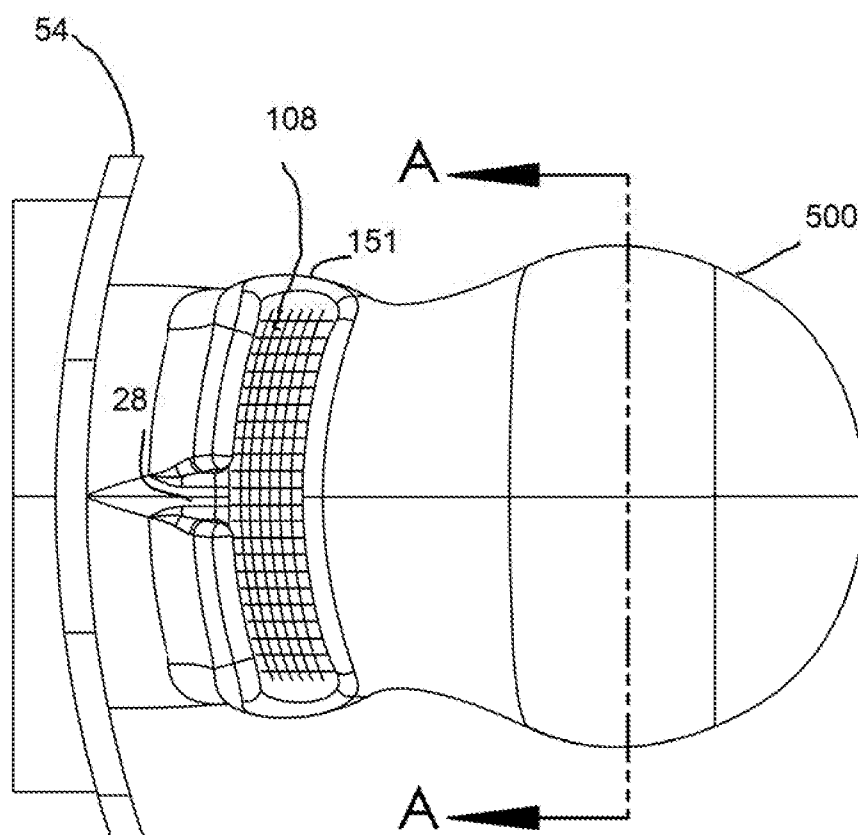
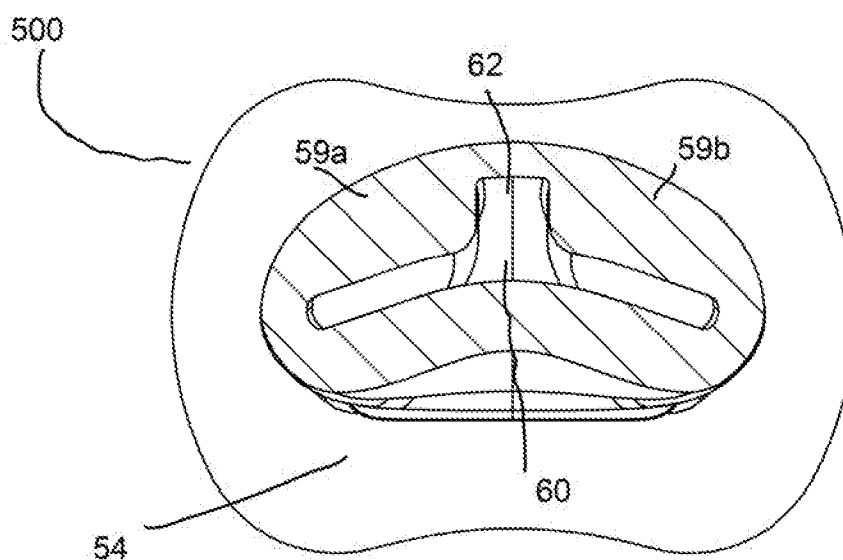


FIG. 37



A-A

FIG. 38

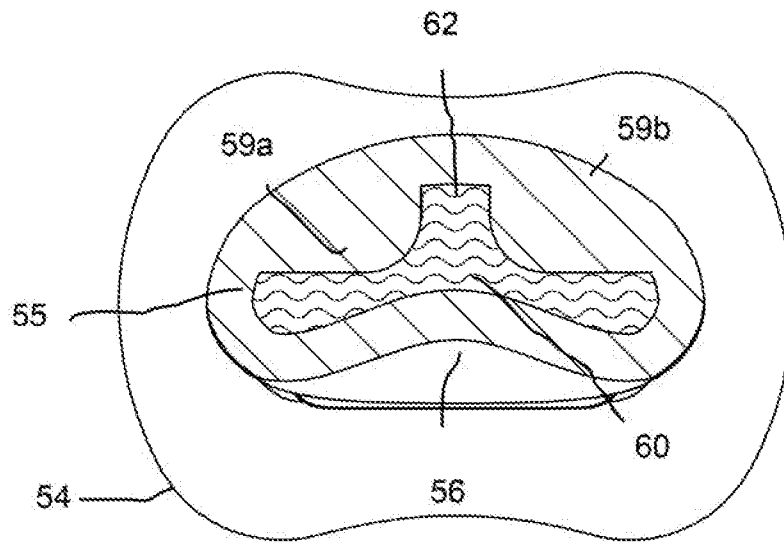


FIG. 39

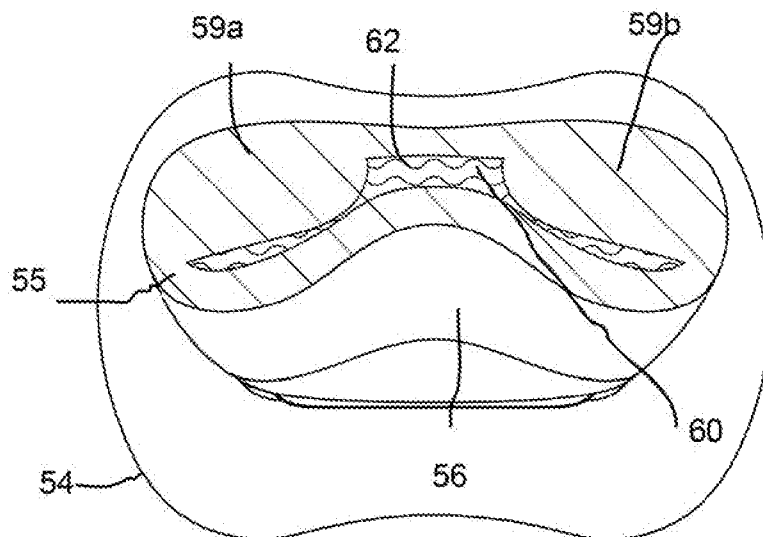


FIG. 40

FIG. 41

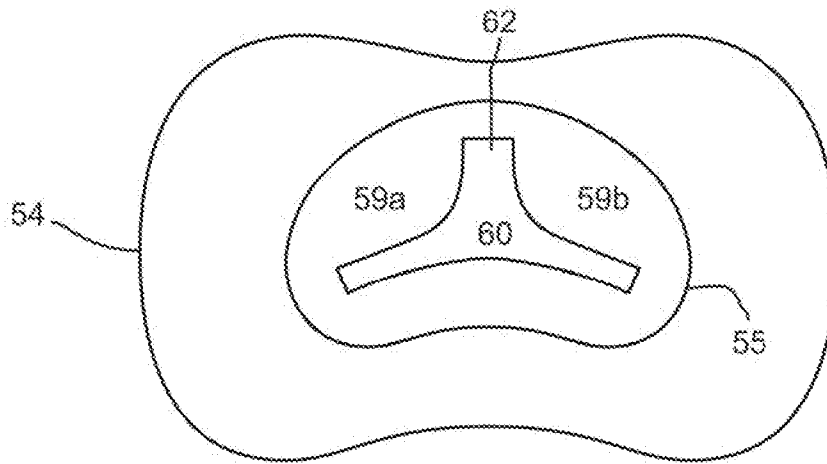


FIG. 42

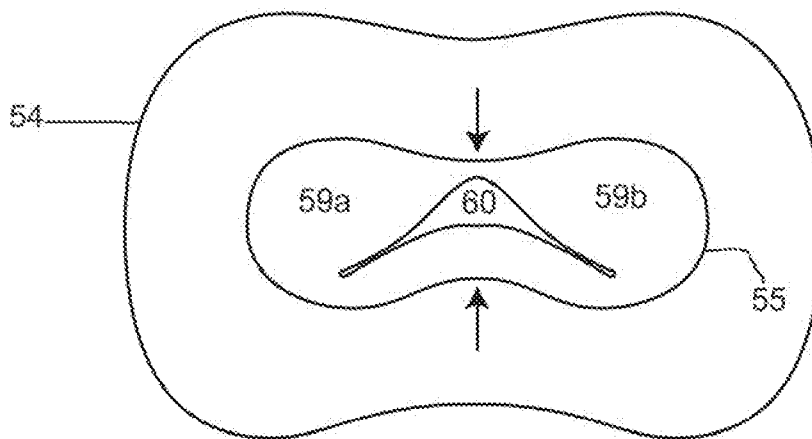


FIG. 43

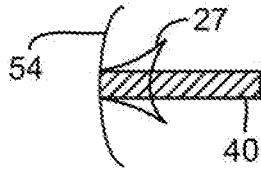


FIG. 44

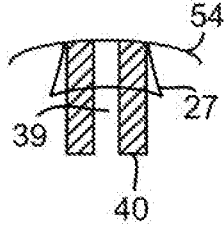


FIG. 45

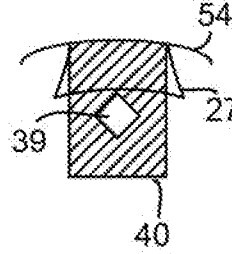


FIG. 46

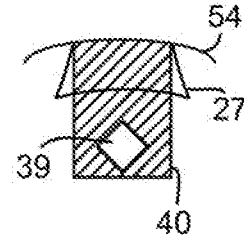


FIG. 47

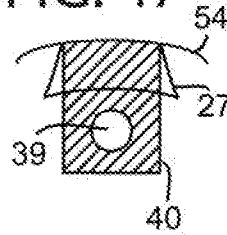


FIG. 48

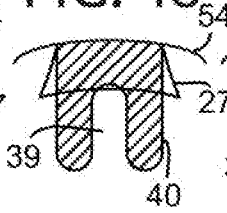


FIG. 49

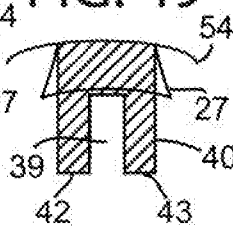


FIG. 50

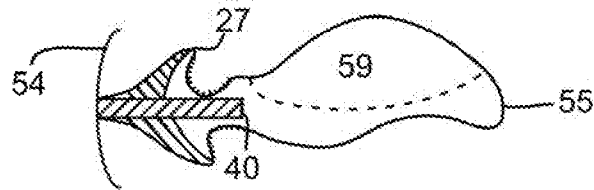


FIG. 51

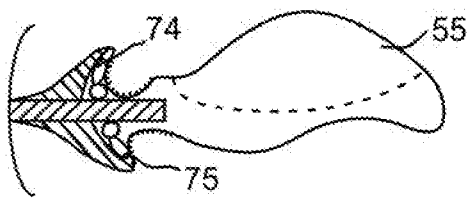


FIG. 53

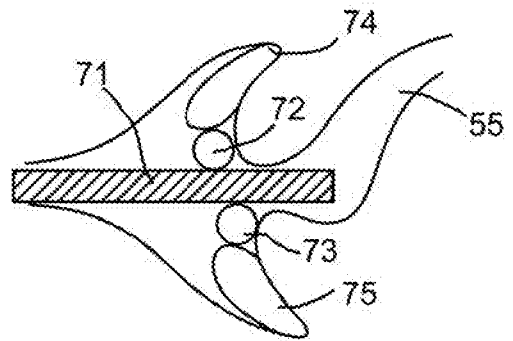
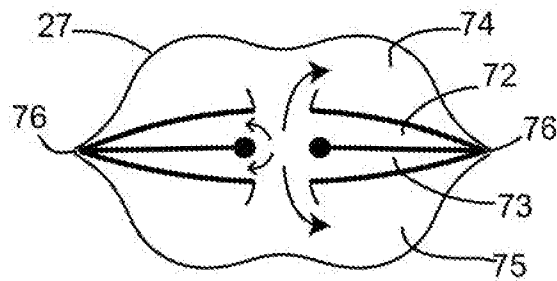


FIG. 52



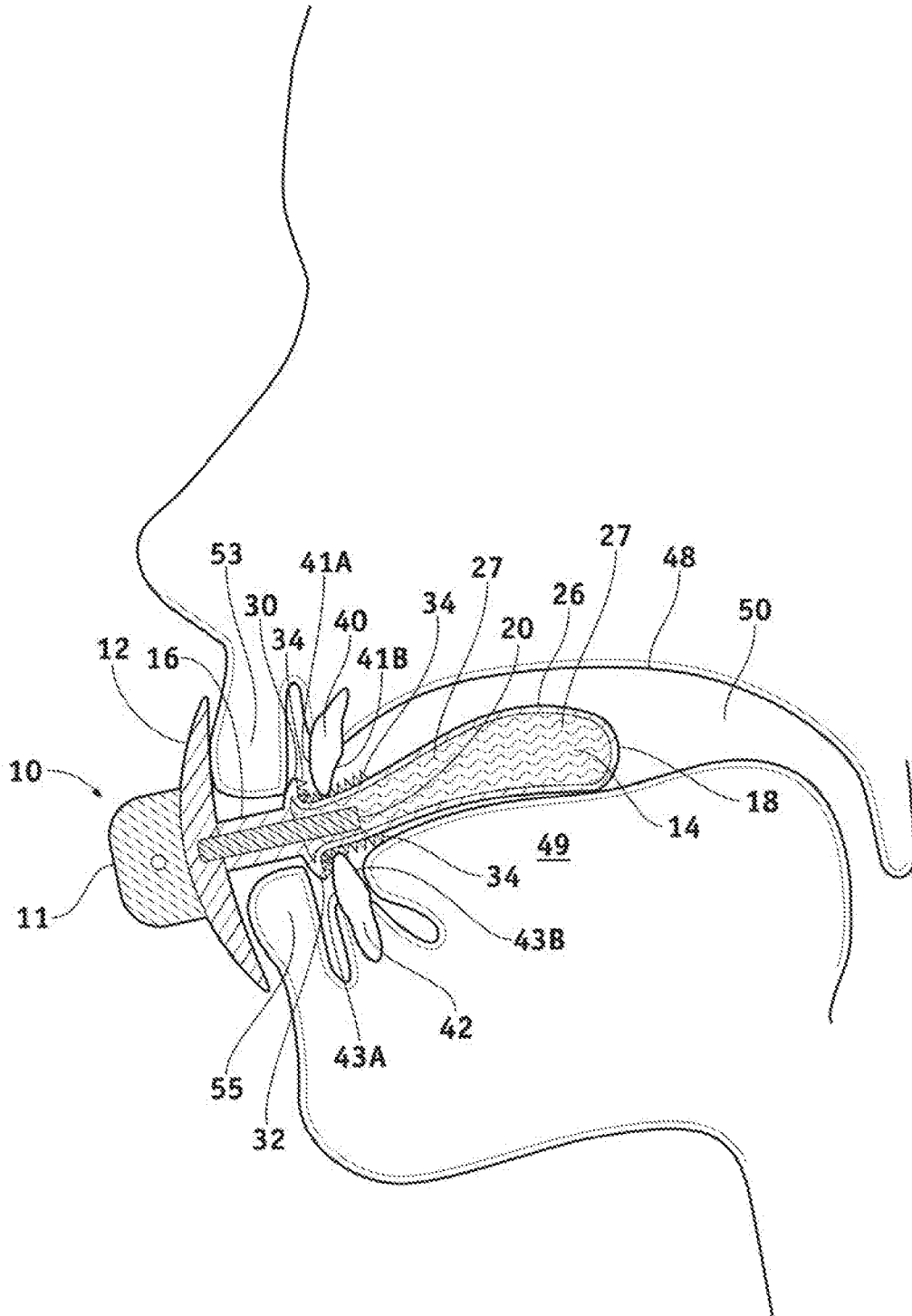
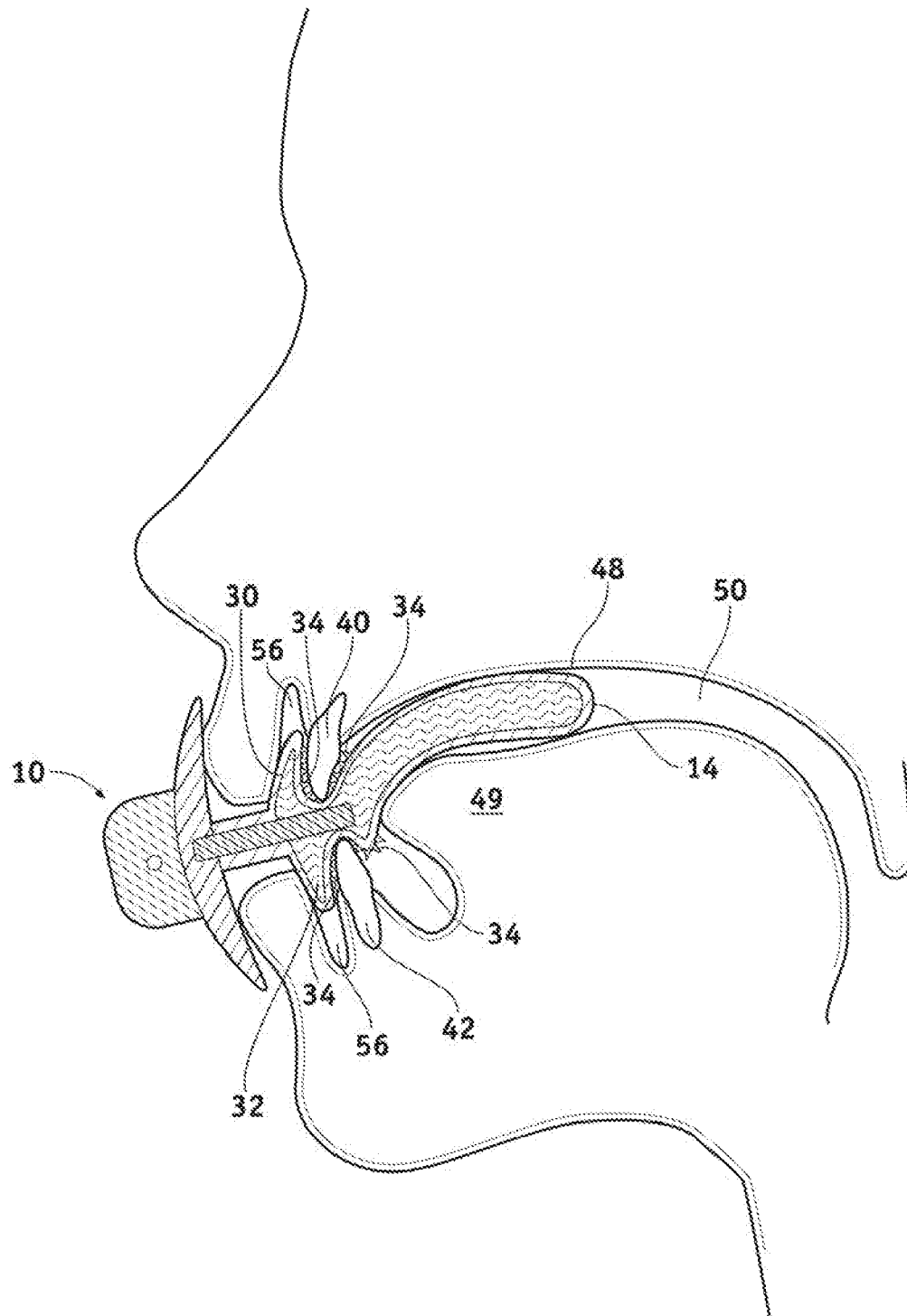


FIG. 54

**FIG. 55**

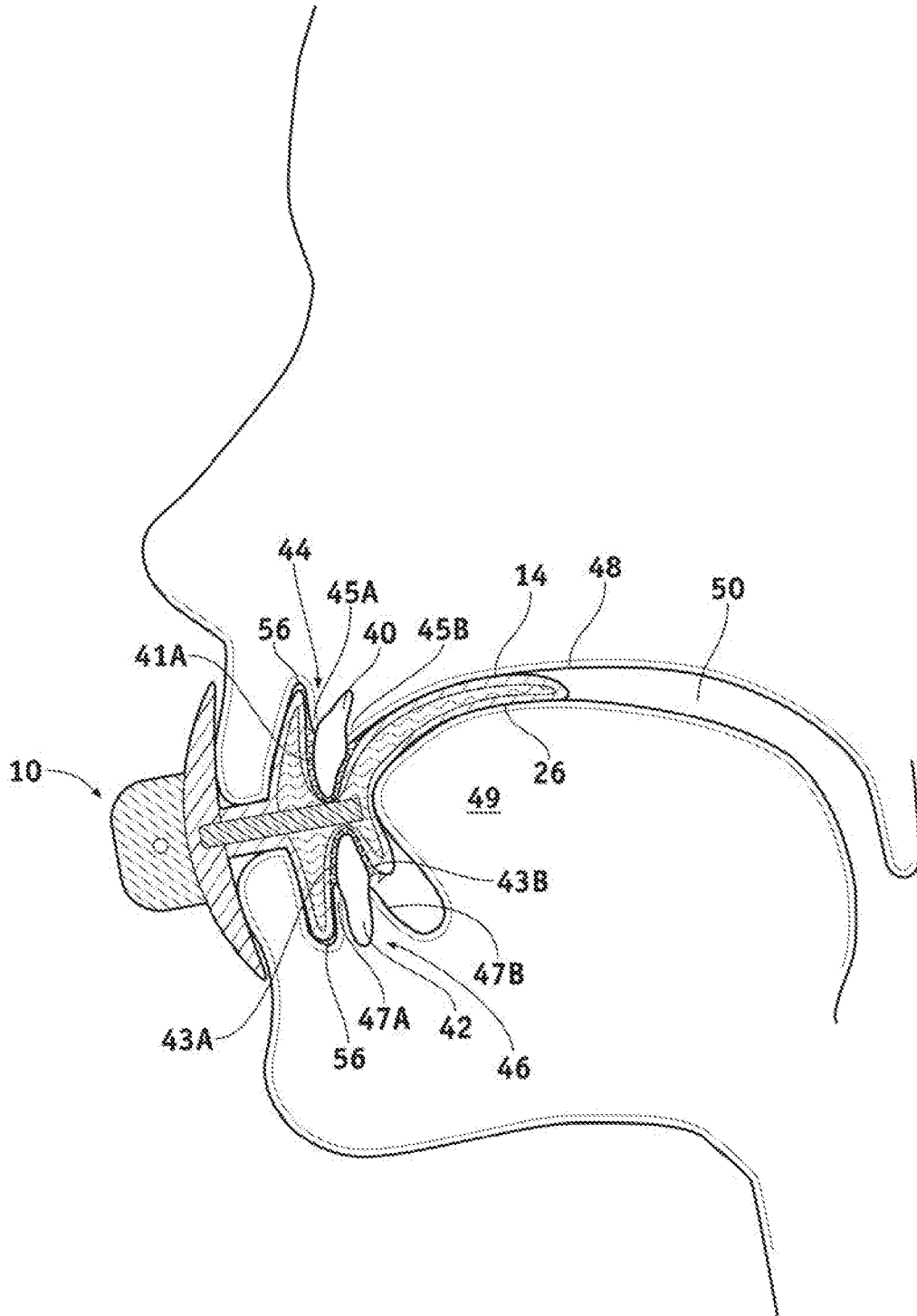
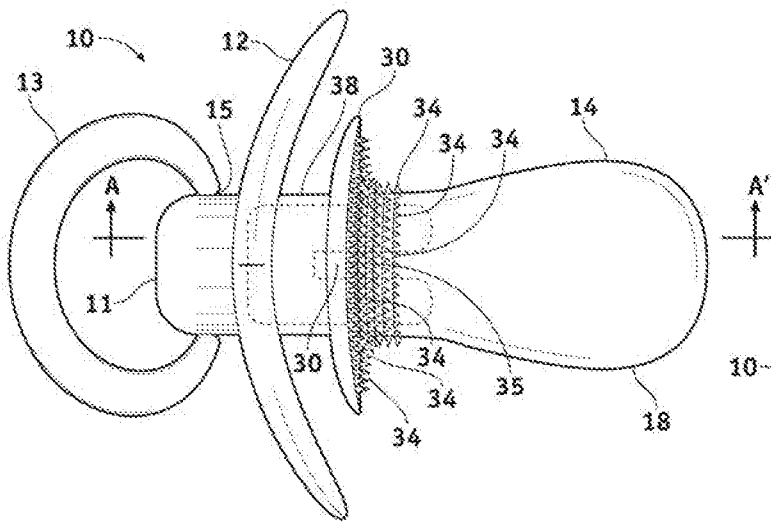
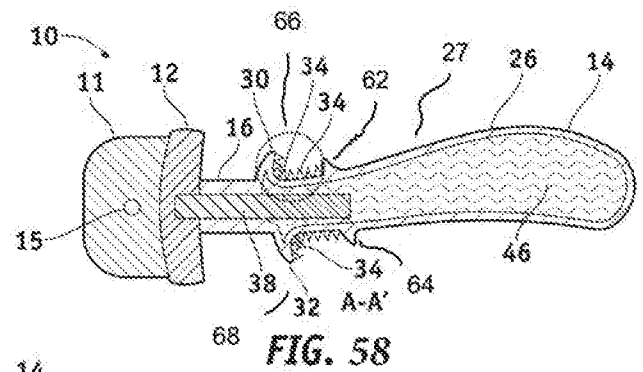
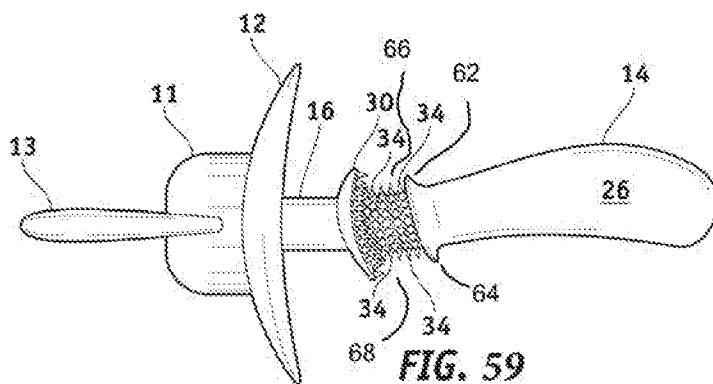
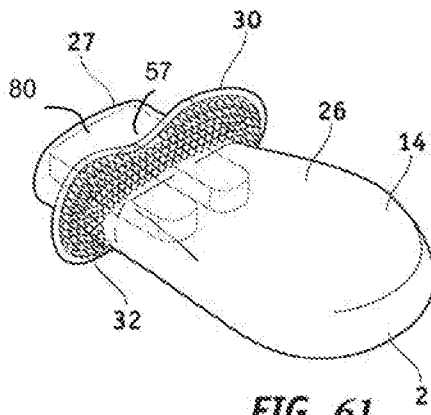
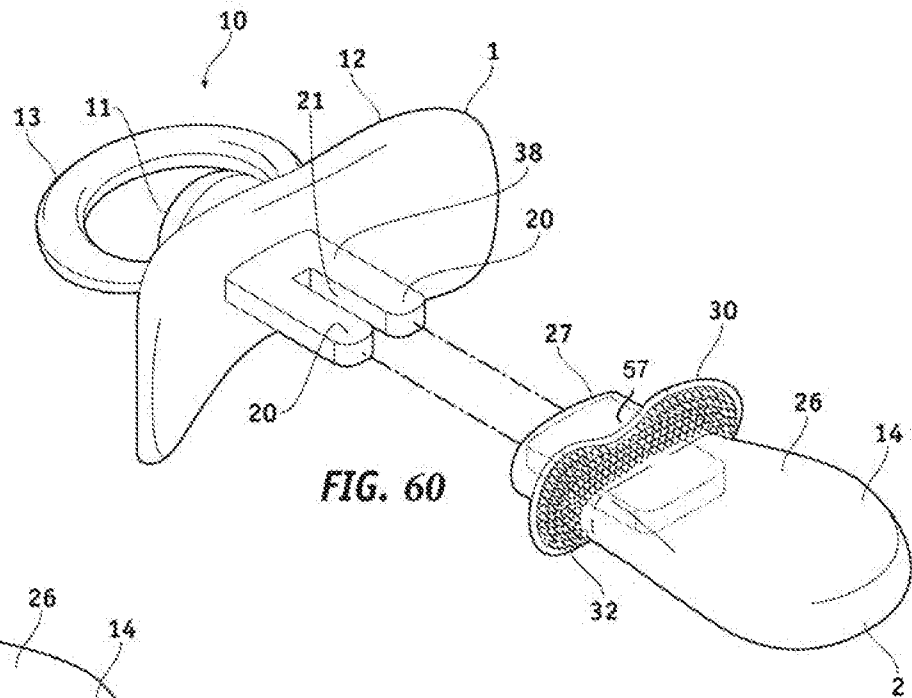
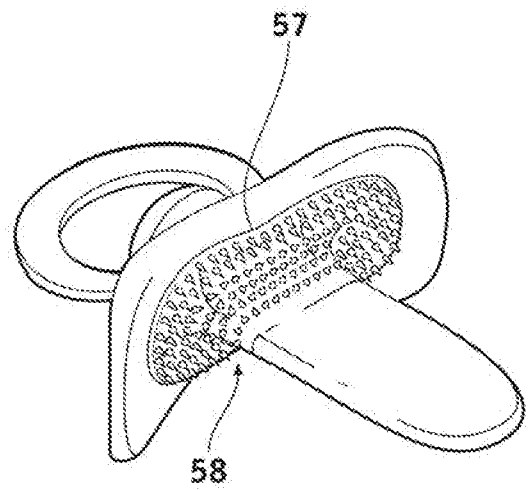
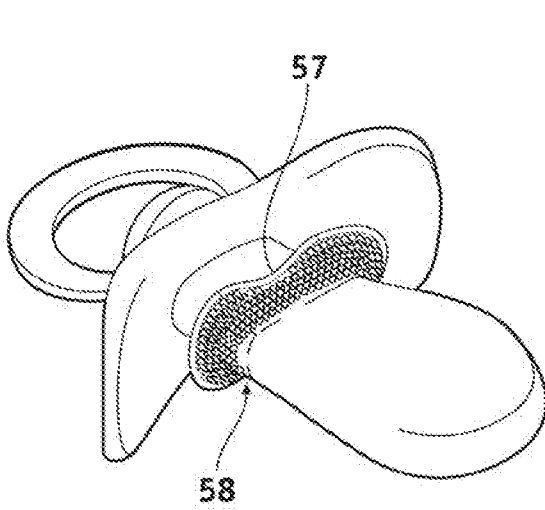
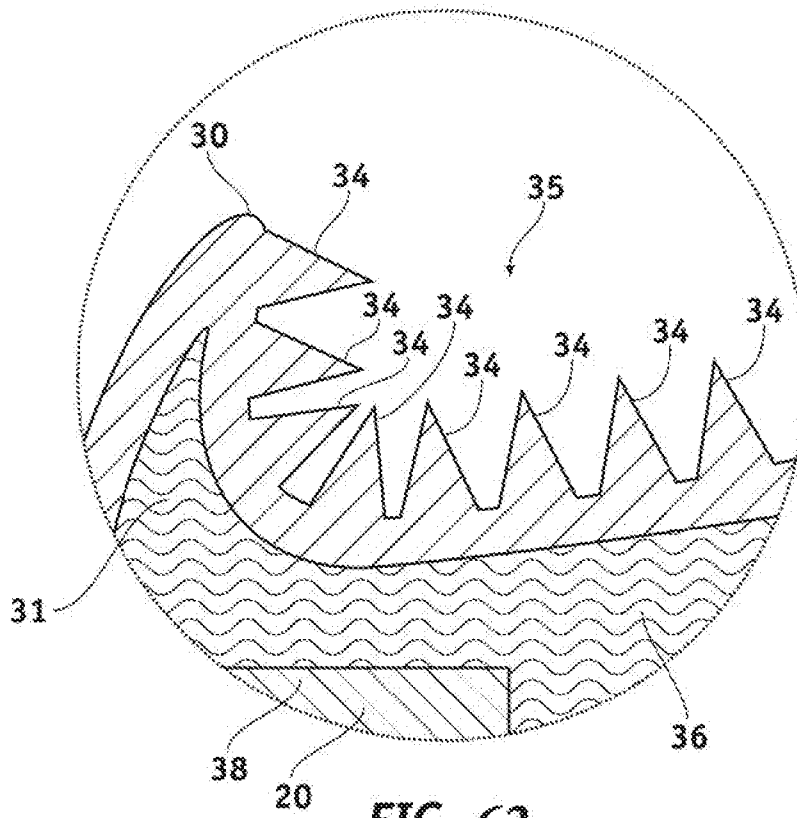
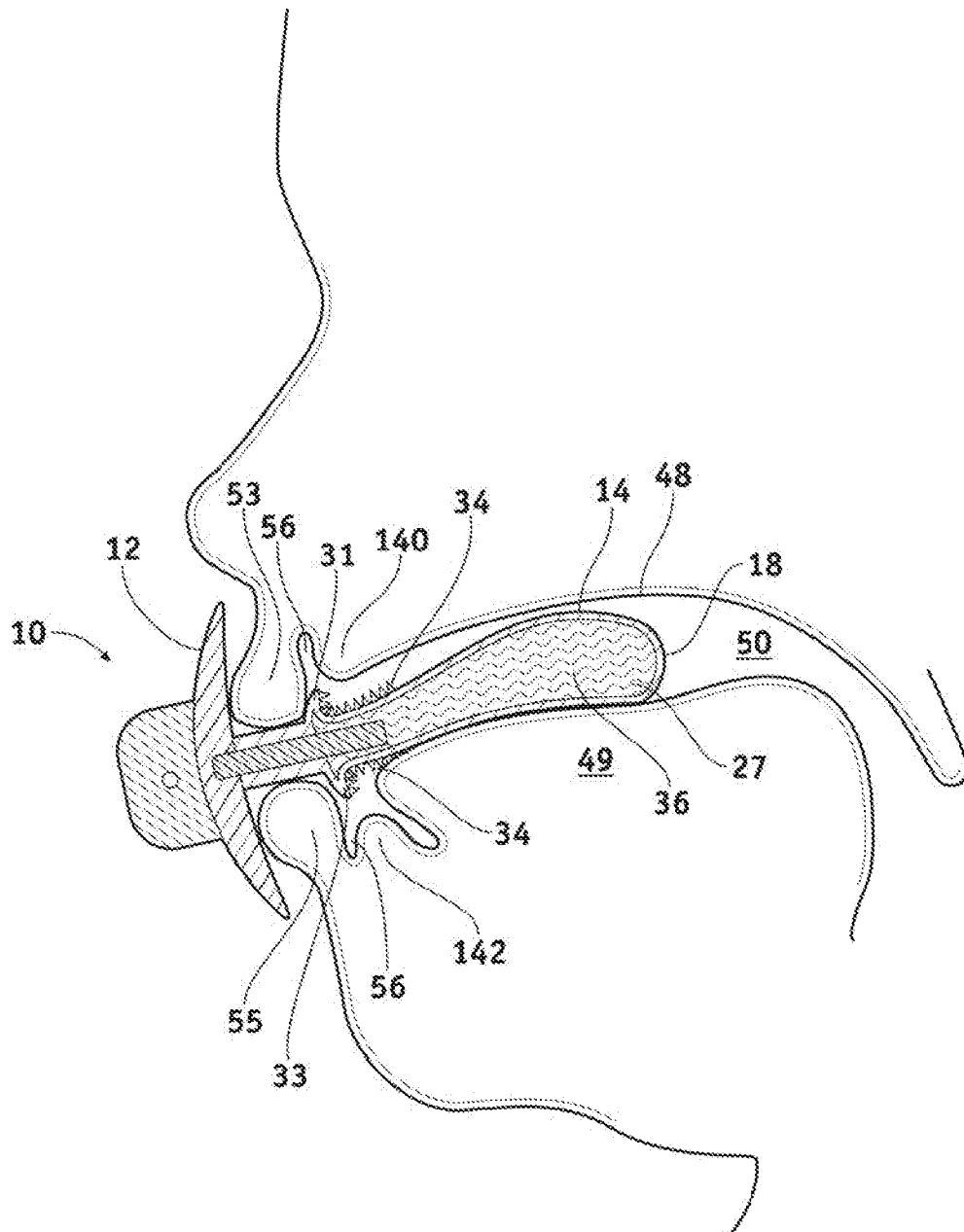


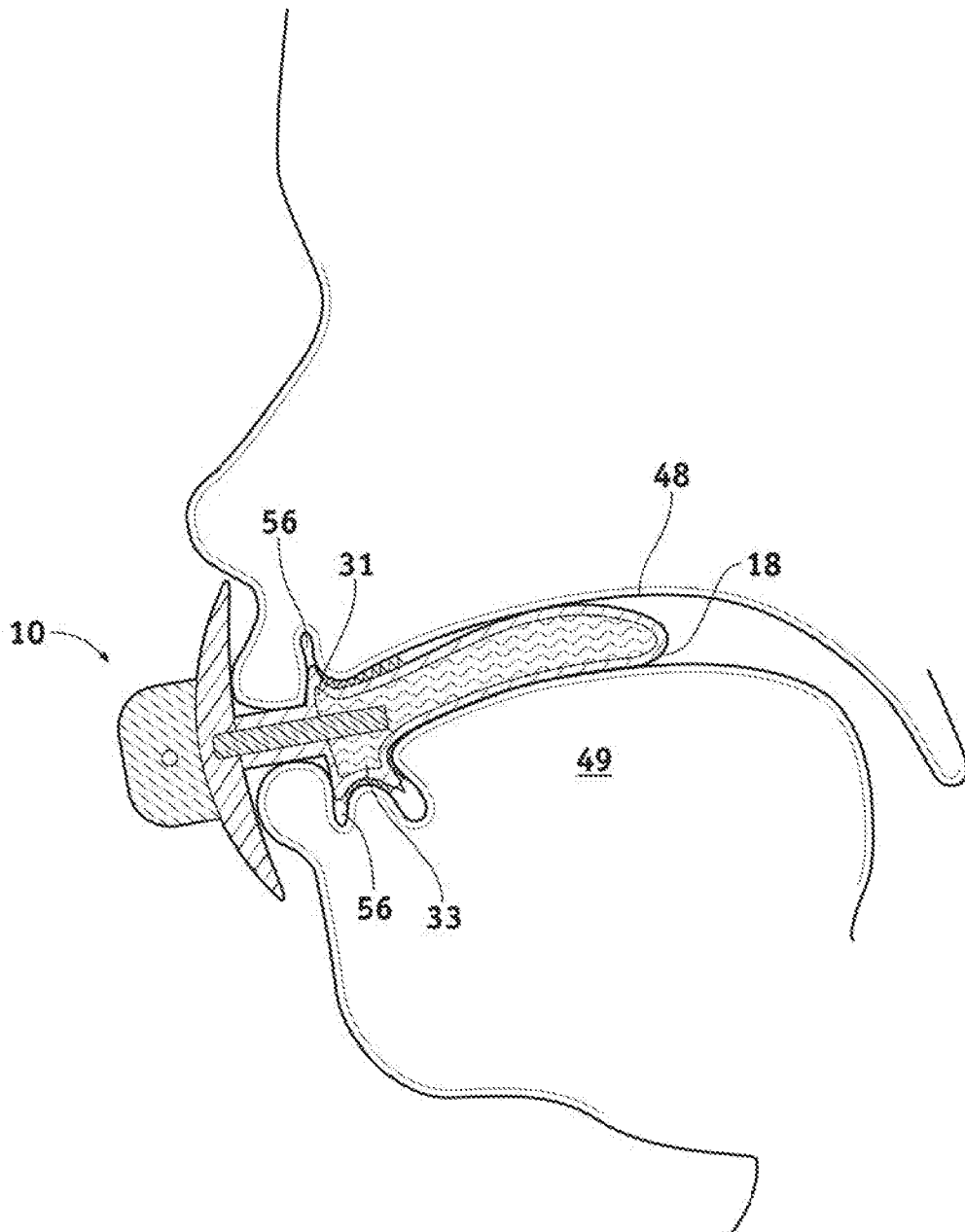
FIG. 56

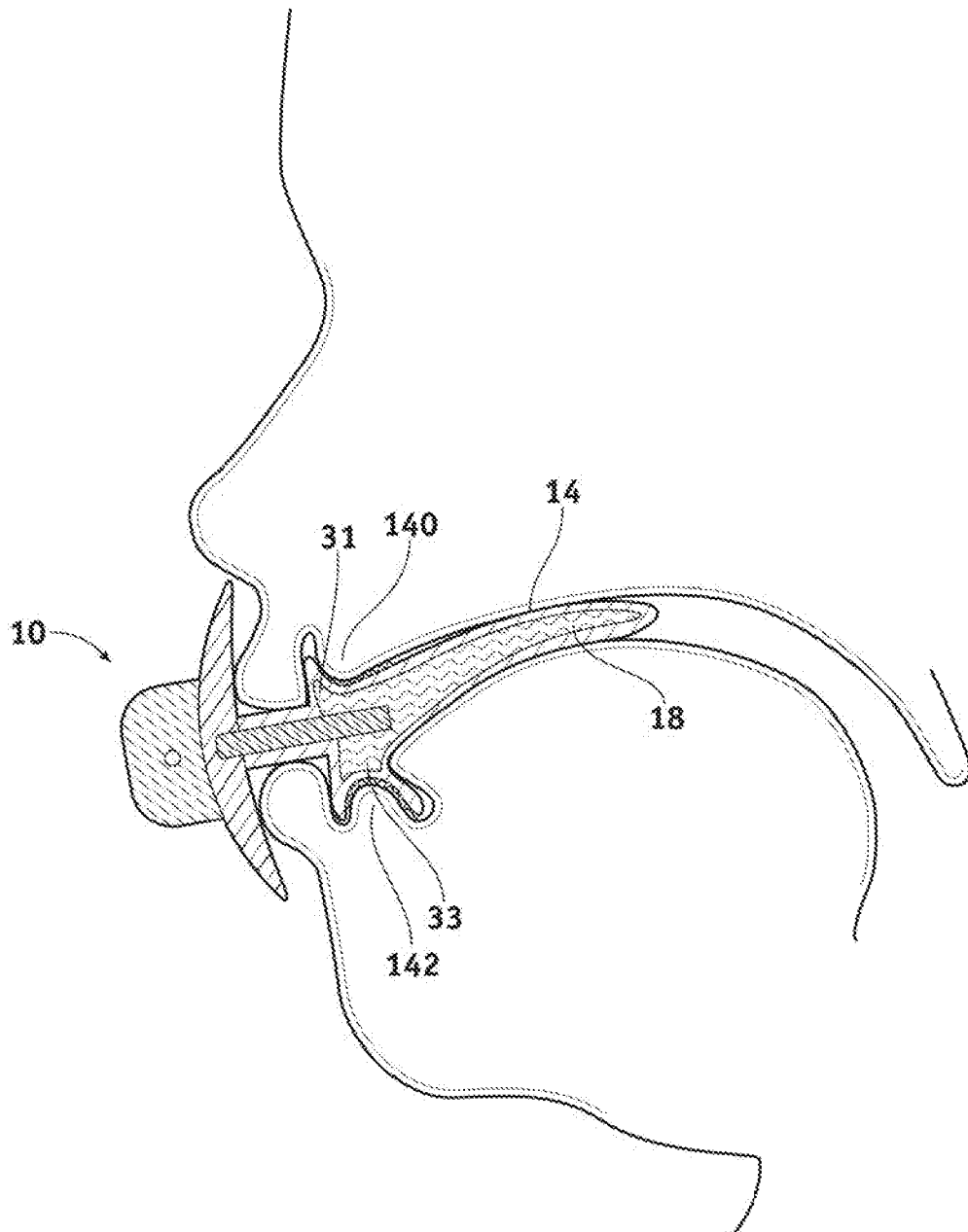
**FIG. 57****FIG. 58****FIG. 59**





**FIG. 65**

**FIG. 66**

**FIG. 67**

