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(54) Title: ARTIFICIAL AIRWAY DEVICE

(57) Abstract: An artificial airway device (1) to facilitate lung ventilation of a patient, comprising an airway tube (2) including a lumen (3), a mask (4) at one end of the airway tube, the mask including a backplate (5) and having a peripheral formation (6) capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen (7) of the mask and the airway tube (2) opening into the lumen of the mask, the device further comprising fixation means (8c) for fixation of the device to a patient when the device is in use, the fixation means being movable with respect to the airway tube to allow for correct positioning of the device with respect to the anatomy of the patient.

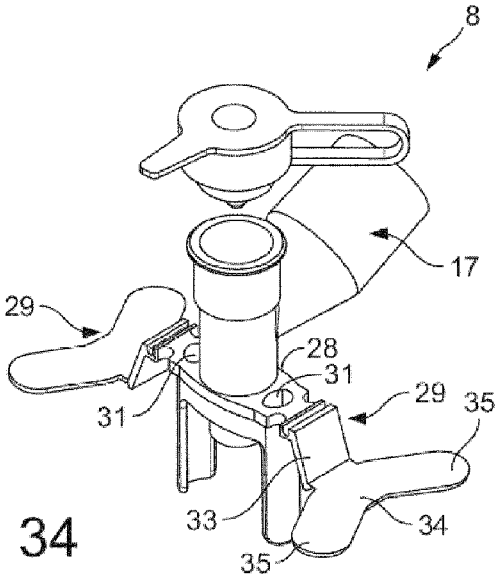

FIG. 34

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ARTIFICIAL AIRWAY DEVICE

The present invention relates to an improved artificial airway device, and in particular to a laryngeal mask that is suitable for use in treatment of paediatric patients.

For at least seventy years, endotracheal tubes comprising a long slender tube with an inflatable balloon disposed near the tube's distal end have been used for establishing airways in unconscious patients. In operation, the endotracheal tube's distal end is inserted through the mouth of the patient, into the patient's trachea. Once positioned, the balloon is inflated so as to form a seal with the interior lining of the trachea. After this seal is established, positive pressure may be applied to the tube's proximal end to ventilate the patient's lungs. Also, the seal between the balloon and the inner lining of the trachea protects the lungs from aspiration (e.g., the seal prevents material regurgitated from the stomach from being aspirated into the patient's lungs).

Although they have been successful, endotracheal tubes suffer from several major disadvantages. The principal disadvantage of the endotracheal tube relates to the difficulty of properly inserting the tube. Inserting an endotracheal tube into a patient is a procedure that requires a high degree of skill. Also, even for skilled practitioners, insertion of an endotracheal tube is sometimes difficult or not possible. In many instances, the difficulty of inserting endotracheal tubes has tragically led to the death of a patient because it was not possible to establish an airway in the patient with sufficient rapidity. Also, inserting an endotracheal tube normally requires manipulation of the patient's head and neck and further requires the patient's jaw to be forcibly opened widely. These necessary manipulations make

it difficult, or undesirable, to insert an endotracheal tube into a patient who may be suffering from a neck injury.

The use of endotracheal tubes in infants can be particularly challenging. Statistics suggest that in general, levels of anaesthesia-related morbidity and mortality are higher in paediatric patients than in adults, as well as in younger compared to older children and this is often due to airway complications, which are more likely in very young infants. Critical events are highest in infants < 2 kg [Tay et. al. Paediatr Anaesth 11: 711, 2001]. In paediatric patients the tongue is relatively larger, more commonly leading to airway obstruction than in adult patients. Paediatric patients often have less pulmonary reserve than adults, and require significantly more oxygen intake, thus they are prone to apnoea during direct laryngoscopy. As the posterior commissure is relatively cephalad, the anterior sublaryngeal airway is predisposed to trauma from an ETT and the narrowest portion of the infant airway is the cricoid cartilage, which can lead to resistance after passing an ETT through the cords.

Children recovering from URI (upper respiratory infection) are at increased risk for respiratory complications. For short procedures via mask, the increased risk is minimal. If reactive airways accompany the infection, the effects of URI may last 2-7 weeks. In particular, those who already have asthma, bronchopulmonary dysplasia, sickle cell, or live in a household of smokers are at high risk, suggesting a “two hit” phenomena [Tait et. al. Anesthesiology 95: 299, 2001]. Bronchial hypereactivity may last as long as 7 weeks after URI [Collier et. al. Am Rev Resp Dis 117: 47, 1978]. Note that in these patients mask anaesthetics have significantly lower complications than an ETT.

If an ETT is required, the risk of anaesthesia in an infant can be increased as much as 10-fold when compared to an infant with no URI and which does not require use of an ETT. Risk of using an LMA are about halfway between those of a facemask and an ETT.

The laryngeal mask airway device is a well known device that is useful for establishing airways in unconscious patients, and which seeks to address some of the known drawbacks associated with endotracheal tubes.

In contrast to the endotracheal tube, it is relatively easy to insert a laryngeal mask airway device into a patient and thereby establish an airway. Also, the laryngeal mask airway device is a "forgiving" device in that even if it is inserted improperly, it still tends to establish an airway. Accordingly, the laryngeal mask airway device is often thought of as a "life saving" device. Also, the laryngeal mask airway device may be inserted with only relatively minor manipulation of the patient's head, neck and jaw. Further, the laryngeal mask airway device provides ventilation of the patient's lungs without requiring contact with the sensitive inner lining of the trachea and the internal diameter of the airway tube is typically significantly larger than that of the endotracheal tube. Also, the laryngeal mask airway device does not interfere with coughing to the same extent as endotracheal tubes. Largely due to these advantages, the laryngeal mask airway device has enjoyed increasing popularity in recent years.

U.S. Patent No. 4,509,514 describes a laryngeal mask airway device which consists of the basic parts which make up most if not all laryngeal mask airway devices, namely an airway tube opening at one end into the interior of a hollow mask portion shaped to fit readily behind

the larynx of a patient. The periphery of the mask is formed by a cuff which in use forms a seal around the opening of the larynx. This enables the airway to be established effectively. More recently, laryngeal masks have been provided with additional features that improve their basic functionality and also add new functionality.

Laryngeal mask airway devices with specific provision for gastric-discharge drainage have been developed, as exemplified by U.S. Pat. No. 4,995,388 (Figs. 7 to 10); U.S. Pat. No. 5,241,956; and U.S. Pat. No. 5,355,879. These devices generally incorporate a small-diameter drainage tube having an end located at the distal end of the mask, so as to lie against the upper end of the upper oesophageal sphincter when the mask is in place, the tube being of sufficient length to extend out of the mouth of the patient to enable active or passive removal of gastric discharge from the upper oesophageal sphincter. According to alternative proposals, the drainage tube may extend beyond the distal end of the mask, into the oesophagus itself (U.S. Pat. No. 4,995,388, Figs. 7 and 11).

Laryngeal mask airway devices are now commonly used to aid in insertion of endotracheal tubes, and such devices are referred to as intubating laryngeal masks, an example being Applicant's own "Fastrach"TM device.

Laryngeal mask airways are now routinely provided with devices to facilitate fixation of the airway to a patient in order to keep it in the correct position when in use. Examples of such devices are shown for example in applicant's own European Patent No. 1663 364B, which illustrates, *inter alia* how fixation means and structures can conveniently be provided in association with the connectors of devices at or adjacent the proximal end of the airway tube.

It is of particular importance to ensure that laryngeal mask airway devices remain stably in the fully inserted configuration because otherwise their correct functioning can be compromised. If the seal around the laryngeal inlet provided by the cuff is disturbed, airway patency may be affected and gastric fluid may be aspirated. This is particularly, although not exclusively, a problem when treating paediatric patients because, due to the smaller scale of both the airway device and the patient, even small inadvertent movements, for example of the proximal end of the airway device, can result in disturbance of the mask and therefore the seal.

The present invention seeks to ameliorate problems associated with the prior-art described above.

According to a first aspect of the invention there is provided an artificial airway device to facilitate lung ventilation of a patient, comprising an airway tube including a lumen, a mask at one end of the airway tube, the mask including a backplate and having a peripheral formation capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen of the mask and the airway tube opening into the lumen of the mask, the device further comprising fixation means for fixation of the device to a patient when the device is in use, the fixation means being movable with respect to the airway tube to allow for correct positioning of the device with respect to the anatomy of the patient.

In one embodiment, the device of the present invention may be sized for use in paediatric patients.

The device is preferably provided with a connector at the proximal end of the airway tube for connection of air supply means and to provide access to the lumen of the airway tube. The fixation means may be provided as a part of the airway tube or as a part of the connector. The fixation means may be an integrally formed part of the airway tube or connector, such as a part of a single moulding, or as an alternative, the fixation means may be a separate part attachable to the airway tube or the connector. Where the fixation means is a separate part, it is preferred that it includes a fixation plate including a major surface adapted to be disposed at or adjacent the proximal end of the airway tube, wherein the major surface of the fixation plate extends along a length which is substantially perpendicular to the longitudinal axis of the device.

It is preferred that the fixation means includes one or more fixation structure for fixation to the patient. The fixation structure may be connected to the airway tube, or where the fixation means includes a fixation plate, it is preferred that the fixation structure is connected to the plate. It is further preferred that the fixation means comprises at least two fixation structures. Where there are two fixation structures, it is preferred that they are disposed opposite, or substantially opposite each other about a periphery of the fixation plate or of the airway tube. The or each fixation structure may comprise one or more generally planar plate. Alternatively, the or each fixation structure may comprise a plate and/or a bar.

It is preferred that the or each fixation structure is movably attached relative to the airway tube or to the connector, and that through such attachment, movement of the or each structure relative to the airway tube is enabled. It is further preferred that the or each fixation structure is movably attached relative to the airway tube or to the connector such that the or each

fixation structure may be moved towards and/or away from the airway tube. Where there are two or more structures, it is preferred that they are movable independently from one another.

It is preferred that the or each fixation structure is movably attached relative to the airway tube or to the connector via a connection point that comprises a hinge. As an alternative, the or each fixation structure may be movably attached relative to the airway tube or connector via a connection point that comprises a tie. Where the connection point comprises a tie, it is preferred that the tie is positioned at or near the centre of the gap between the structure and its point of attachment to the connector or airway tube.

It is preferred that the or each hinge or tie comprises a pliant or bendable material, more preferably a plastics material.

It is preferred that the or each connection point provides for relative movement between its respective structure and the airway tube about at least a single hinge axis. It is further preferred that the or each connection point provides for relative movement between its respective structure and the airway tube about a first hinge axis and a second hinge axis perpendicular to the first hinge axis. It is most preferred that the or each connection point provides for relative movement between its respective structure and the airway tube about a first hinge axis, a second hinge axis perpendicular to the first hinge axis and a third hinge axis, perpendicular to the first and second hinge axes, giving complete freedom of movement.

Where there are a plurality of fixation structures, a plurality of connection points giving different ranges of movement may be used. The provision of movable fixation structures

means that a precise positioning and fit of the airway device to the patient, taking into account the particular anatomy of the patient, can be established, which is particularly important in paediatric patients.

Where the or each fixation structure comprises a tab, it is further preferred that the or each tab may itself include one or more sub tab, movably attached thereto.

The connector may include one or more port to provide access to the lumen of the airway tube. At least one port may include means to reduce its internal volume. For example, the port may include a bore and the internal volume reduction means may comprise an insert in the bore. This is advantageous because it reduces the dead space in the air supply system which is particularly important for paediatric patients, whilst retaining the standard outer diameter of the connector.

It is preferred that the peripheral formation comprises an inflatable cuff, or a non-inflatable cuff. It is further preferred that where the peripheral formation comprises an inflatable cuff, the backplate overlies the cuff and is bonded to it, such that on deflation the cuff may be collapsed upon it, thereby encouraging the cuff to pack flat.

According to a second aspect of the invention there is provided a method of treating a patient using a device as defined hereinabove.

The invention will now further be described by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a dorsal isometric view of a device according to the invention;

Figure 2 is a dorsal view of the device of Figure 1;

Figure 3 is a ventral isometric view of the device of Figure 1;

Figure 4 is a left side view of the device of Figure 1;

Figure 5 is a right side view of the device of Figure 1;

Figures 5a to 5f are transverse sectional views along long lines 1-1 to 6-6 in Figure 5;

Figure 6 is a right side exploded view of the device of Figure 1;

Figure 7a is a front isometric view of a part of the device of Figure 1;

Figure 7b is a dorsal view of the part shown in Figure 7a;

Figure 7c is a right side view of the part shown in Figure 7a;

Figure 7d is a rear isometric view of the part shown in Figure 7a;

Figure 7e is a front view of the part shown in Figure 7a;

Figure 8a is a dorsal view of a further part of the device of Figure 1;

Figure 8b is a transverse sectional view along line C-C in Figure 8a;

Figure 8c is a longitudinal sectional view along line B-B in Figure 8a;

Figure 8d is a front dorsal isometric view of the part shown in Figure 8a;

Figure 9 is a rear ventral isometric view of the part shown in Figure 8a;

Figure 10 is a rear view of the part shown in Figure 8a;

Figure 11 is dorsal view of a yet further part of the device shown in Figure 1;

Figure 12 is a longitudinal sectional view along line D-D in Figure 11;

Figure 13 is a transverse sectional view along line E-E in Figure 12;

Figure 14 is a front dorsal isometric view of the part shown in Figure 11;

Figure 15 is a right side ventral isometric view of the part shown in Figure 11;

Figure 16 is a ventral isometric view of the part shown in Figure 11;

Figure 16a is a ventral view of the part shown in Figure 11;

Figure 16b is a left side ventral isometric view of the part shown in Figure 11;

Figure 17 is a right side exploded view of a second embodiment of device according to the invention;

Figure 18 is a dorsal view of a part of the device shown in Figure 17;

Figure 19 is a longitudinal sectional view along line F-F in Figure 18;

Figure 20 is a transverse sectional view along line G-G in Figure 19;

Figure 21 is a ventral view of the part shown in Figure 18;

Figure 22 is a front dorsal isometric view of the part shown in Figure 18;

Figure 23 is a right side ventral isometric view of the part shown in Figure 18;

Figure 24 is a ventral view of the part shown in Figure 18;

Figure 25 is a dorsal view of a further part of the device shown in Figure 17;

Figure 26 is a longitudinal sectional view along line H-H in Figure 25;

Figure 27 is a ventral view of the part shown in Figure 25;

Figure 28 is a transverse sectional view along line I-I in Figure 26;

Figure 29 is a front dorsal isometric view of the part shown in Figure 25;

Figure 30 is a right side ventral isometric view of the part shown in Figure 25;

Figure 31 is a right side rear ventral isometric view of the part shown in Figure 25;

Figure 32 is a front view of the connector shown in Figures 6 and 17;

Figure 33 is a longitudinal sectional view along line J-J in Figure 32;

Figure 34 is a top plan isometric view of the connector shown in Figures 6 and 17;

Figure 35 is an under plan isometric view of the connector shown in Figures 6 and 17;

Figure 36 is a top plan isometric view of a second form of connector for use in a device according to the invention;

Figure 37 is a top plan view of the connector of Figure 36;

Figure 38 is a side view of the connector of Figure 36; and

Figure 39 is sectional view along line B-B in Figure 38.

In the discussion of the following exemplary embodiments, like parts will generally be given the same reference numerals throughout the description.

For convenience of exposition, referring to Figures 1 to 4, reference letter A denotes the dorsal surface of the device. Reference letter B denotes the ventral surface of the device. In accordance with standard practice, that part of the device 1 that in use will extend from the patient is referred to herein as the proximal end (in the sense that it is nearest the user) with the other end being referred to as the distal end. In Figure 2, reference letter C denotes the right side and reference letter D denotes the left side.

Referring to the drawings, there is illustrated an artificial airway device 1 to facilitate lung ventilation of a patient, comprising an airway tube 2 including an airway tube lumen 3, a mask 4 at one end of the airway tube, the mask including a backplate 5 and having a peripheral formation 6 capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen 7 of the mask and the airway tube 2 opening into the lumen of the mask 4, the device further comprising fixation means 8c for fixation of the device to a patient when the device is in use, the fixation means being movable with respect to the airway tube to allow for correct positioning of the device with respect to the anatomy of the patient.

It will be understood that as described here, the invention is demonstrated in a particular type of laryngeal mask airway device, namely a device that in some respects is adapted specifically for paediatric usage and also includes provision for removal of gastric material or to provide gastric access. The skilled person will understand that the invention is not limited in applicability to specifically this type of device.

Device 1 includes a connector 8 disposed at the proximal end of the airway tube 2, the connector 8 including a main bore 9 for passage of gas to the airway tube lumen 3, the main bore 9 including a wall 10 defining a circumference and including a plurality of ports 12 to allow passage of gas to the main bore, at least one port 12 being disposed for circumferential rotational movement about the main bore 9.

Connector 8 is illustrated in detail in Figures 32 to 35. Referring to Figures 32 and 33, connector 8 comprises five parts, namely access port part 8a, main bore part 8b, fixation means 8c, insert part 8d and plug 8e. With the exception of the plug 8e, each part may be injection moulded from polypropylene or polyethylene. Plug 8e is preferably formed from silicone by liquid injection moulding, transfer moulding or compression moulding.

Access port part 8a comprises a main tube 13 including a generally cylindrical wall 10 having a bore 19 and respectively an outer larger diameter part 15, an inner smaller diameter part 16, and a branch tube 17. Branch tube 17 defines branch bore 18 and is attached to inner smaller diameter part 16 such that branch bore 18 is in fluid communication with bore 19. Branch tube 17 includes an outer constant diameter section 20 that is dimensioned to connect to a standard gas supply. Constant diameter section 20 is connected to a frustoconical section 21

that in turn connects to wall 10. Inner smaller diameter part 16 includes inner circumferential groove 22 adjacent distal end.

Main bore part 8b comprises a tubular wall 23 defining a bore 24 and proximal and distal ends 25, 26. Proximal end 25 is dimensioned to be received within bore 19 of access port part 8a and includes outer circumferential ridge 27 that is dimensioned to fit into inner circumferential groove 22 of access port part 8a.

Fixation means 8c comprises generally rectangular fixation plate 28, and fixation structure which in this first embodiment takes the form of fixation tabs 29.

Plate 28 includes a central through-bore 30 and two side through-bores 31 which extend between the major surfaces of the plate. Fixation tabs 29 extend from the minor end surfaces of the plate 28, and are hingedly attached thereto by thin plastic webs 32. Each fixation tab 29 comprises a connector plate 33, a lower plate 34 and tabs 35. As viewed in Figures 32 to 35, and when in use in a patient, connector plate 33 depends downwardly from its proximal hinged attachment point at a minor end surface of plate 28 at a resting angle of greater than 90 degrees thereto. At its distal end each connector plate 33 is further hingedly attached to a lower plate 34, the surface of which is disposed at rest substantially parallel to, but at a lower level than, the surface of plate 28. Each lower plate 34 comprises two sub tabs 35 which are co-planar with plate 34 at rest and hingedly attached thereto via hinge points 36 (Figure 35).

Referring to Figure 35, insert part 8d comprises an ellipsoidal mounting ring 37 having a circumferential wall 38 and depending legs 11. Each depending leg 11 comprises an arcuate wall.

Referring to Figure 33, plug 8e comprises a circular cup insert 39 that is dimensioned to fit via an interference fit into bore 19 of access port 8a. Insert 39 includes a bottom surface 40 with a centrally disposed through-bore 41 and a circumferential wall 42. Wall 42 includes a circumferential skirt 43 depending from its upper, as viewed edge 44, thereby defining a downwardly open channel 45 between skirt and wall. Plug 8e further comprises cap 46 which is attached by retaining strap 47 to skirt 43 and is dimensioned to fit within cup insert 39. Cap 46 includes depending knob 48 which fits within through-bore 41 when the cap is in place in the plug.

The parts are assembled by forming a connector 8 comprising an access port part 8a, main bore part 8b, fixation means 8c and insert part 8d. The plug component 8e of the connector comprises a circular cup insert 39 that is dimensioned to fit via an interference fit into bore 19 of access port 8a. The plug 8e is attached by a retaining strap 47 to skirt 43 and is dimensioned such that it fits within cup insert 39. Cap 46 including a depending knob 48 fits within through bore 41 when the cap is in place in the plug.

The connector 8 is inserted into the airway tube by inserting the insert part 8d into a recess provided at the distal end of the airway tube 2. The insert part 8d comprises depending legs 11, each depending leg 11 comprising an arcuate wall and being dimensioned such that the insert part 8d fits within the recess of the airway tube. The insert part of the connector passes

through the central through-bore 30 of the fixation part 8c. The fixation means 8c is positioned at the proximal end of the airway tube, wherein the major surface of the fixation plate 28 extends along a length which is substantially perpendicular to the longitudinal axis of the laryngeal mask airway device. Fixation tabs 29 extend from the minor surfaces of the plate 28 and are hingedly attached thereto by webs 32. Each fixation tab comprises a connector plate 33, a lower plate 34 and tabs 35. With reference to Figures 32 to 35 and when in use in a patient, the connector plate 33 depends downwardly from its proximal hinged attachment point at a minor end surface of plate 28 at a resting angle of greater than 90 degrees thereto. At its distal end, each connector plate is further hingedly attached to a lower plate 34, the surface of which is disposed at rest substantially parallel to, but at a lower level than, the surface of plate 28. Each lower plate comprises two tabs 35 which are co-planar with plate 34 at rest and hingedly attached thereto via hinge points (Figure 35).

Referring in particular to Figures 1 to 5, the device 1 as illustrated comprises an airway tube 2 and a mask 4 provided at one end of the airway tube, the mask including a backplate 5 and having a peripheral formation 6 capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen 7 of the mask and the airway tube opening into the lumen of the mask 4, and a connector 8 disposed at the proximal end of the airway tube, the connector 8 including a main bore 9 for passage of gas to the airway tube lumen 3, the main bore including a wall defining a circumference and including a plurality of ports 12 to allow passage into the main bore, at least one port 12 being disposed for circumferential rotational movement about the main bore 9.

At its distal end, airway tube 2 is attached to mask 4. Airway tube 2 and mask 4 may be formed integrally or separately. It will be noted that airway tube 2 terminates towards the proximal end of mask 4. Thus mask 4 does not suffer in terms of being made too rigid by the material of the airway tube. One notable feature of the present invention is the construction of the backplate 5. As the skilled worker will appreciate, the term "backplate", when used in the present technical field has come to denote that part of the mask that is surrounded by the cuff in the assembled device and which provides separation between the laryngeal and pharyngeal regions when the device is in situ in the patient. Supply of gas takes place through an aperture in the backplate via a fluid tight connection between the part of the backplate defining the aperture and the airway tube. In one known arrangement the backplate and airway tube are formed integrally which is a particularly convenient arrangement. In the prior art, backplates are generally bowl or dome shaped structures rather than flat structures and the term is therefore not entirely descriptive of the shape.

The device further comprises a component 240 for monitoring the pressure of the cuff to check that the cuff has been inflated correctly.

In the embodiment as shown in Figures 1 to 5, the device includes a dual gastric drain 60 in the form of a softly pliant sleeve that terminates at its distal end in atrium 58. Thus, the device of Figures 1 to 5 comprises two gastric drain tubes 60.

In the presently described embodiment backplate 5 comprises inner and outer skins 5a, 5b that together define a space therebetween, as shown schematically in Figures 5a to 5f. The space so defined is atrium 58 from which proximally, drain tubes 60 lead off and distally, inlet 58a

enters. The atrium can be regarded as a manifold that connects the single gastric inlet 58a with the gastric drain tubes 60. The gastric drain tubes 60 and backplate may be integrally formed.

Airway tube 2 is formed from a material such that it is not collapsible and has a preformed fixed curve as illustrated in Figure 1. As an example, the airway tube 2 may be of 80 Shore A durometer according to ASTM 2240. The airway tube may be formed from any known suitable material such as PVC or silicone.

As mentioned above, mask 4 includes peripheral formation 6 which in this embodiment takes the form of an inflatable cuff of generally known form. Cuff 6 includes an inflation line 6a at its proximal end and has a gastric inlet aperture 6b at its distal end (Figure 3). Referring to the exploded view in Figure 5, it can be seen that the dorsal surface of cuff 6 is bonded to backplate 5 so that the material of the dorsal surface of the cuff 6 forms a bridge between the inner and outer skins 5a, 5b thus closing off the ventral side of atrium 58 except where gastric inlet aperture 6b enters the cuff. Thus it can be seen that gastric inlet 6b is in fluid communication with atrium 58. In an alternative method of construction the cuff 6 may be formed with a web across its aperture that itself forms the ventral surface of atrium 58.

Figure 6 shows an exploded view of the device of Figures 1 to 5 to demonstrate how the parts of the device are fitted together. From the exploded view of Figure 6 it can be seen that the device 1 comprises three main parts, a gastric drain and airway tube and backplate combination part 2, 60, 5a; an inner backplate wall 5b, and a peripheral formation 6, as well as the connector 8. From these it can be seen that the outer backplate part 5a, and inner

backplate wall 5b are combined to form the backplate 5, thus defining a conduit in the form of chamber or atrium 58 within the backplate 5. The peripheral part 6, in this embodiment an inflatable cuff, is attached to the backplate 5 by bonding to the attachment surface 122 such that the backplate 5 seats within it.

The gastric drain and airway tube and backplate combination part 2, 60, 5a consists of a precurved tube 101. The tube 101 is not circular in cross-section but has a flattened section, as taught in previous patents, for ease of insertion and fit through the interdental gap. The tube 101 has flattened dorsal and ventral surfaces 101a, 101b and curved side walls 101c extending from a proximal end 101d to a distal end 101e. At its distal end the combination part 2, 60, 5a is cut at an angle relative to its longitudinal axis to provide an outer backplate part 5a which may be integrally formed therewith, for example by molding. As an alternative the outer backplate part 5a can be separately formed, for example, from a transparent or translucent material. The outer backplate part 5a may include a circumferential lip. Finally, with reference to Figure 11, it will be noted that gastric drain, airway tube and backplate combination part includes a substantially coaxially disposed inner tube extending from the distal end to the proximal end, the inner tube effectively establishing a separation of the inner space into two gastric conduits 106 and an airway conduit 107. This arrangement is further illustrated in Figures 12 and 13 and 14 to 16b, wherein Figure 12 shows the view through Section D-D of Figure 11 and Figure 13 shows the view through Section E-E of Figure 12.

Referring now to Figures 8a to 8d and Figures 9 and 10, there is illustrated inner backplate wall 5b. Inner backplate wall 5b comprises a generally elliptical body in the form of a shallow dish including side wall 111 and floor 112. At the distal, or narrower end of the elliptical dish,

side wall 111 has a cylindrical aperture 111a formed therein that extends distally generally in line with the midline of the floor 112. It will be noted that cylindrical aperture 111a may be angled upwardly, relative to the plane of the floor 112 such that the angle of the axis of the bore of the cylindrical aperture is about 20 degrees relative thereto. Along its midline the floor 112 of the dish is raised to form a convex surface that extends longitudinally towards the wider, proximal end where it terminates in a cylindrical formation that may be referred to as a tube joint 113. Tube joint 113 includes bore 113a that provides a connecting passage between the upper and lower surfaces (as viewed) of floor 112. Tube joint 113 merges with and bisects side wall 111 and is angled upwardly at about 45 degrees relative to floor 112, terminating proximally some distance beyond the side wall 111 as shown in Figure 9.

Referring now to Figures 7a to 7e, there is illustrated peripheral formation 6 which in this embodiment takes the form of an inflatable cuff. It will be noted that unlike many other laryngeal mask airway devices the cuff 6 is formed integrally as a separate part from the rest of the device, making it easier both to manufacture and attach to the device 1. The cuff 6 comprises a generally elliptical body with a narrower distal end 120a, a wider proximal end 120b and a central elliptical through-aperture 120c. As such it will be appreciated that the cuff resembles a ring. As can be seen from the sectional view in Figure 7c, the elliptical body comprises a wall 123 that is generally circular in section at the distal end but deeper and irregularly shaped at the proximal end by virtue of an integrally formed extension 121 formed on the dorsal surface at the proximal end 120b. This dorsal surface extension 121 defines the proximal portion of an attachment surface 122 (Figures 6 and 7a). The attachment surface 122 extends from the proximal end to the distal end around the entire dorsal inner circumference of the ring. At its distal end 120a the cuff has a cylindrical through bore 121 the axis of which

extends in line with the midline of the ellipse and is angled upwardly as viewed in Figure 7c relative to the plane of the body, in other words from the ventral towards the dorsal side or when the device 1 is in use from the laryngeal to the pharyngeal side of the anatomy (L and P in Figure 7c). The result is a circular section aperture through the cuff wall 123. The proximal end 120b of the cuff includes a port 124 that lets into the interior of the bore and the cuff. As illustrated, for example, in Figures 7a, 7b and 7d, the cuff comprises side projections 160 which help to prevent the occlusion of the airway by supporting the anatomy of the patient.

Thus, in this device, the airway tube, gastric drain and backplate combination part comprises the airway tube and the gastric drain tubes. It has been found that contrary to expectation it is most important in a device having a gastric tube that flow of gastric material should not be impeded, so that the seal formed around the upper oesophageal sphincter is not broken. This arrangement best utilises the available space within the anatomy to achieve this end. Similarly, the provision of an atrium 58 to receive gastric flow as opposed to the simple uniform section conduits of prior devices provides a mask that is in effect a hollow leak-free plug against the upper oesophageal sphincter, with a low-flow high-volume escape route above it. The device 1 of this embodiment of the invention enables a user to get such a plug into place and hold it there whilst providing a sufficiently generous escape path for emerging fluids. Further still, it has been found that the provision of a gastric inlet port that is angled dorsally as described further aids in ensuring that the seal around the upper oesophageal sphincter remains intact even under heavy load, particularly when an atrium is provided directly upstream therefrom.

In use, the device 1 is inserted into a patient to establish an airway as with prior art devices. Insertion is effected to the point where gastric inlet aperture 6b meets the patient's oesophageal sphincter, thus establishing fluid communication therebetween. If vomiting or regurgitation occurs, as with previous gastric access laryngeal masks, the material from the oesophagus passes into gastric inlet aperture 6b. Once the device 1 is in the desired position, the fixation means 8c is used to secure it there against further movement. Fixation structures 29 are positioned against the cheeks of the patient on either side of the patient's mouth using the connection points so that the surfaces of the fixation structures are oriented as far as is possible, flat against the surfaces of the skin. The fixation structures can then be taped in place, or secured using a tape passed around the patient's head, to keep the device 1 securely in postion.

Referring now to Figures 17 to 31, there is illustrated a further alternative embodiment of device 400 according to the invention.

With reference to Figure 17, it can be seen that the device 400 resembles other laryngeal mask airway devices. The device of Figure 17 is similar to the previously described embodiments and comprises an airway tube and backplate combination part. However, instead of being integrally formed as in the previously described embodiments, in the embodiment of Figure 17 the airway tube and backplate combination part includes two pieces: an outer sheath and an inner core, wherein the inner core includes an airway lumen. From the exploded view of Figure 17 it can be seen that the device 400 comprises an airway tube and backplate combination part 200, an inner core element 202, an inner backplate wall part 5b, a peripheral formation 6, and a connector 8. In this embodiment, the airway tube comprises an outer part

200 and an inner core 202, the inner core defining an airway lumen 210. At least one gastric conduit 260 is defined by the inner core 202, or a combination of the inner core 202 and the outer tube part 200.

The peripheral formation 6 of this embodiment comprises the features as described in previous embodiments. The airway tube and backplate combination part 200 forms an outer sheath or tube component, into which may be inserted the inner core element 202 and inner backplate wall 5b. In the embodiment shown in Figure 17, the inner core element 202 and inner backplate wall 5b may be integrally formed. However, in other embodiments, the inner core element 202 and inner backplate wall 5b may be formed separately and subsequently attached.

The inner core element 202 defines an airway lumen 210 (see Figure 23). The inner core element 202 is dimensioned to fit inside the airway tube and backplate combination part 200. The inner core element 202 extends substantially along the entire length of the airway tube and backplate combination part 200. When the inner core element is inserted within the airway tube and backplate combination part, the inner core element provides strength and rigidity to the airway tube and backplate combination part. In addition, the inner core element 202 allows for flexibility of use, allowing a plurality of conduits to be defined within the core element to allow for passage of gastric matter, introduction of sensors, introduction of viewing devices, etc.

The inner core element further comprises two grooves 212, each groove extending along each of the left and right sides of the inner core element 202. In the embodiment where the inner

core element is inserted within the outer sheath component of the airway tube and backplate combination part 200, the combination of the inner core element 202 and outer tube part 200 forms a gastric conduit for passage of gastric matter. In the embodiment shown in Figure 17, the insertion of the inner core into the airway tube and backplate combination part results in the formation of two gastric conduits.

As illustrated, for example, in Figures 27, 30 and 31, the inner surface of the airway tube and backplate combination part 200 comprises at least one track 220 to facilitate insertion of the inner core 202. Advantageously, the at least one track 220 on the inner surface of the airway tube and backplate combination part 200 guides and facilitates insertion of the inner core element 202. The provision of at least one track 220 on the inner surface of the airway tube and backplate combination part 200 may further provide a means for securing the inner core 202 in place during use of the device.

In another embodiment, the inner core element 202 further defines an additional lumen adapted to receive a sensor or viewing device (224), as shown for example in Figure 21. In one embodiment, the sensor may be a temperature sensor. In one embodiment, the device of the present invention may be used with an endotracheal tube.

Referring now to Figures 37 to 39, there is illustrated a further form of fixation means 8c. As shown here, fixation means 8c also includes a generally rectangular fixation plate 28 and fixation structure, but here the fixation structure takes the form of tabs 50 and curved bars 51.

Plate 28 again includes a central through bore 30 and two side bores 31 which extend between the major surfaces of the plate. Generally planar fixation tabs 50 extend from the minor end surfaces of the plate 28 and are hingedly/pivotably attached thereto by thin plastic ties 52. Each tie comprises a narrow, short strip of plastic that extends between tab and plate, at or near the centre of the gap between them. The ties are dimensioned to sufficiently pliant that relative movement between the fixation structure 29 and, ultimately, the airway tube, is possible. The near-abutting minor end surfaces of the plate and tab thus linked together further include indentations 53 on each side of each tie 52 which have the effect of increasing their length. Each tab 50 includes a through bore 54 and, at its distal minor end surface, a fixation bar 51 is rigidly attached. Each bar 51 is generally circular in section and curves away from its respective tab 50 in a shallow arc. Each end 55 of each bar 51 is smoothed and rounded off.

In use, a device 1 according to the invention having this form of fixation means 8c is inserted into a patient to establish an airway as with prior art devices. Insertion is effected to the point where gastric inlet aperture 6b meets the patient's oesophageal sphincter, thus establishing fluid communication there between. If vomiting or regurgitation occurs, as with previous gastric access laryngeal masks, the material from the oesophagus passes into gastric inlet aperture 6b. Once the device 1 is in the desired position, the fixation means 8c is used to secure it there against further movement. Fixation structures 29 are positioned against the cheeks of the patient on either side of the patient's mouth using the connection points so that the surfaces of the fixation structures are oriented as far as is possible, flat against the surfaces of the skin. In this case, as will be appreciated, each tie 52 provides for relative movement between its respective fixation structure 29 and the airway tube about a first hinge axis, a

second hinge axis perpendicular to the first hinge axis and a third hinge axis, perpendicular to the first and second hinge axes, as shown by arrows X,Y and Z, giving complete freedom of orientation of each bar 51.

The fixation structures 29 can then be taped in place, or secured using a tape passed around the patient's head, to keep the device 1 securely in postion.

Features of the above-described embodiments may be re-combined into further embodiments falling within the scope of the present invention. Further, the present invention is not limited to the exemplary materials and methods of construction outlined above in connection with the exemplary embodiments, and any suitable materials or methods of construction may be employed. For example, although the cuff may be formed using a sheet of soft flexible silicone rubber, other materials such as latex or PVC may be used. PVC as a material is particularly suited to embodiments intended for single use, whereas the use of silicone rubber is preferred although not essential for embodiments intended to be re-used in a number of medical procedures.

Further, and as would be appreciated by the skilled person, various features of the present invention are applicable to a wide range of different laryngeal mask airway devices, and the invention is not limited to the exemplary embodiments of types of mask described above. For example, aspects of the invention may be applied to laryngeal mask airway devices featuring epiglottic elevator bars over the mask aperture, which bars are operable to lift the epiglottis of a patient away from the aperture upon insertion of an endotracheal tube or other longitudinally-extended element inserted through the airway tube so as to emerge into the

hollow or lumen of the mask through the mask aperture. Aspects of the present invention may for example be applied to single or re-useable devices, devices featuring aperture bars or not, "intubating" devices which permit an endotracheal tube or similar to be introduced into the larynx via an airway tube of a mask, devices incorporating fiberoptic viewing devices and so forth, without restriction or limitation on the scope of the present invention.

Claims

1. An artificial airway device to facilitate lung ventilation of a patient, comprising an airway tube including a lumen, a mask at one end of the airway tube, the mask including a backplate and having a peripheral formation capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen of the mask and the airway tube opening into the lumen of the mask, the device further comprising fixation means for fixation of the device to a patient when the device is in use, the fixation means being movable with respect to the airway tube to allow for correct positioning of the device with respect to the anatomy of the patient.

2. A device according to claim 1, wherein the device is sized for use in paediatric patients.

3. A device according to claim 1 or 2, wherein the device is provided with a connector at the proximal end of the airway tube for connection of air supply means and to provide access to the lumen of the airway tube.

4. A device according to claim 3, wherein the fixation means is provided as part of the airway tube or as part of the connector.

5. A device according to claim 3 or 4, wherein the fixation means is an integrally formed part of the airway tube or the connector, such as part of a single moulding.

6. A device according to claim 3 or 4, wherein the fixation means is a separate part, attachable to the airway tube or the connector.

7. A device according to claim 6, wherein the fixation means comprises a fixation plate including a major surface adapted to be disposed at or adjacent the proximal end of the airway tube, wherein the major surface of the fixation plate extends along a length which is substantially perpendicular to the longitudinal axis of the device.

8. A device according to claim 7, wherein the fixation means includes one or more fixation structure for fixation to the patient.

9. A device according to claim 8, wherein the fixation structure is connected to the airway tube.

10. A device according to claim 8, wherein the fixation structure is connected to the fixation plate.

11. A device according to claim 8, 9 or 10, wherein the fixation means comprises at least two fixation structures.

12. A device according to claim 11, wherein the fixation structures are disposed opposite, or substantially opposite each other about a periphery of the fixation plate or of the airway tube.

13. A device according to any one of claims 8 to 12, wherein the or each fixation structure comprises one or more generally planar plate.

14. A device according to any one of claims 8 to 13, wherein the or each fixation structure comprises a plate and/ or a bar.

15. A device according to any one of claims 3 to 14, wherein the or each fixation structure is movably attached relative to the airway tube or to the connector, and wherein through such attachment, movement of the or each structure relative to the airway tube is enabled.

16. A device according to claim 15, wherein the or each fixation structure is movable towards and/ or away from the airway tube.

17. A device according to any one of claims 11 to 16, wherein the fixation structures are movable independently from one another.

18. A device according to claim 15, 16 or 17, wherein the or each fixation structure is movably attached relative to the airway tube or to the connector via a connection point that comprises a hinge.

19. A device according to claim 15, 16 or 17, wherein the or each fixation structure is movably attached relative to the airway tube or connector via a connection point that comprises a tie.

20. A device according to claim 19, wherein the tie is positioned at or near the centre of the gap between the structure and its point of attachment to the connector or airway tube.

21. A device according to claim 18, 19 or 20, wherein the or each hinge or tie comprises a pliant or bendable material.

22. A device according to claim 21, wherein the or each hinge or tie comprises a plastics material.

23. A device according to any one of claims 18 to 22, wherein the or each connection point provides for relative movement between its respective structure and the airway tube about at least a single hinge axis.

24. A device according to any one of claims 18 to 23, wherein the or each connection point provides for relative movement between its respective structure and the airway tube about a first hinge axis and a second hinge axis perpendicular to the first hinge axis.

25. A device according to any one of claims 18 to 24, wherein the or each connection point provides for relative movement between its respective structure and the airway tube about a first hinge axis, a second hinge axis perpendicular to the first hinge axis, and a third hinge axis perpendicular to the first and second hinge axes.

26. A device according to any one of claims 8 to 25, wherein the fixation structure comprises a tab.

27. A device according to claim 26, wherein the tab comprises one or more sub tab, movably attached thereto.

28. A device according to any one of claims 3 to 27, wherein the connector comprises one or more port to provide access to a lumen of the airway tube.

29. A device according to claim 28, wherein the at least one port includes means to reduce the internal volume.

30. A device according to claim 29, wherein the at least one port comprises a bore and the means to reduce the internal volume comprises an insert in the bore.

31. A device according to any preceding claim, wherein the peripheral formation comprises an inflatable cuff, or a non-inflatable cuff.

32. A device according to claim 31, wherein when the peripheral formation comprises an inflatable cuff, the backplate overlies the cuff and is bonded to it, such that on deflation the cuff may be collapsed upon it, thereby encouraging the cuff to pack flat.

33. A method of treating a patient using a device according to any one of claims 1 to 32.

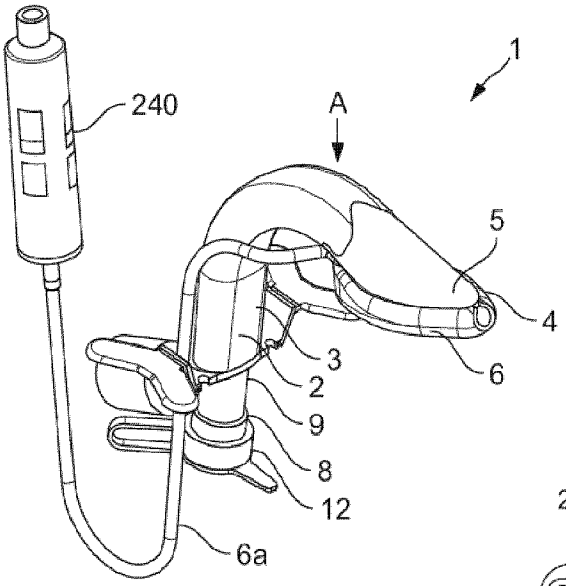


FIG. 1

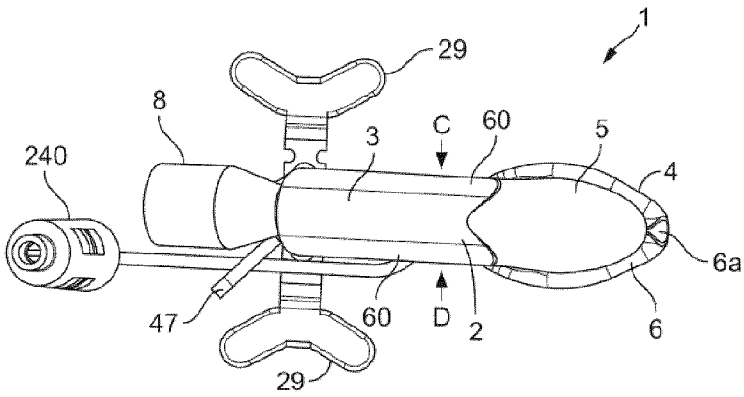


FIG. 2

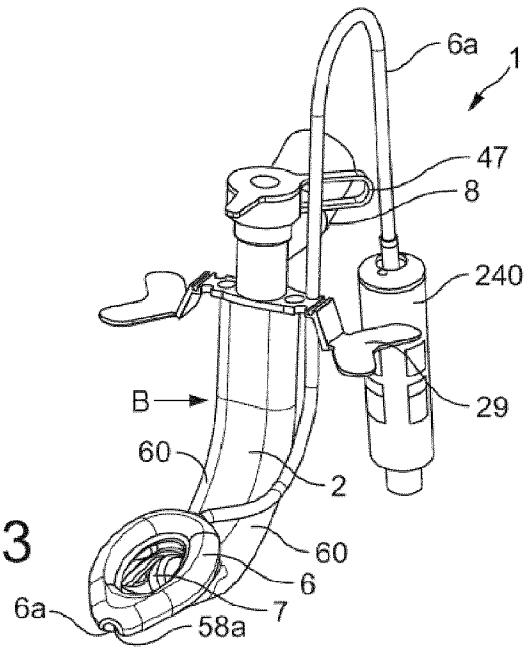


FIG. 3

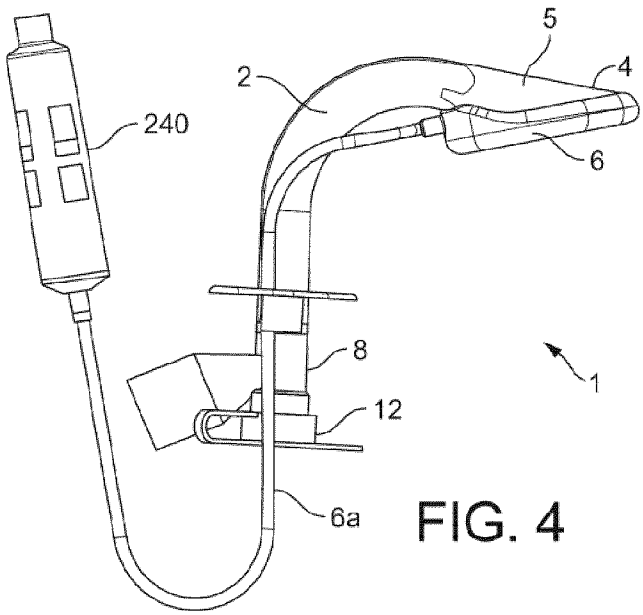


FIG. 4

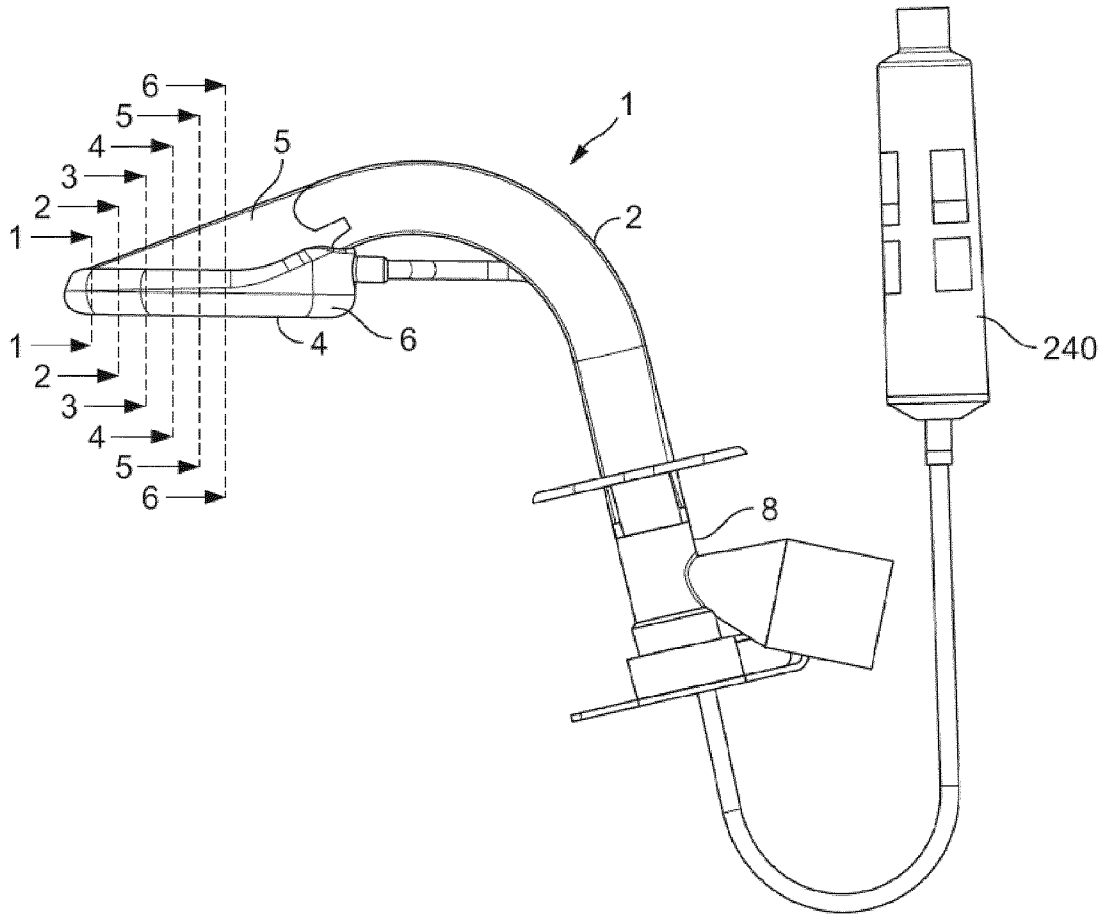
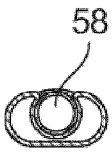
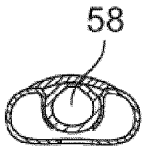


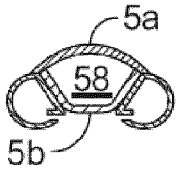
FIG. 5



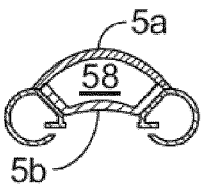
SECTION 1-1
FIG. 5a



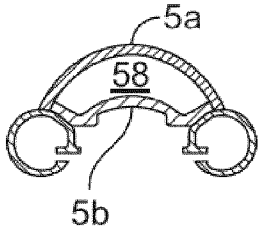
SECTION 2-2
FIG. 5b



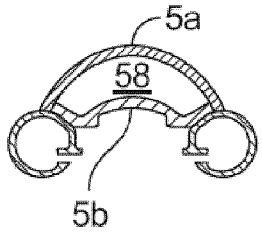
SECTION 3-3
FIG. 5c



SECTION 4-4
FIG. 5d



SECTION 5-5
FIG. 5e



SECTION 6-6
FIG. 5f

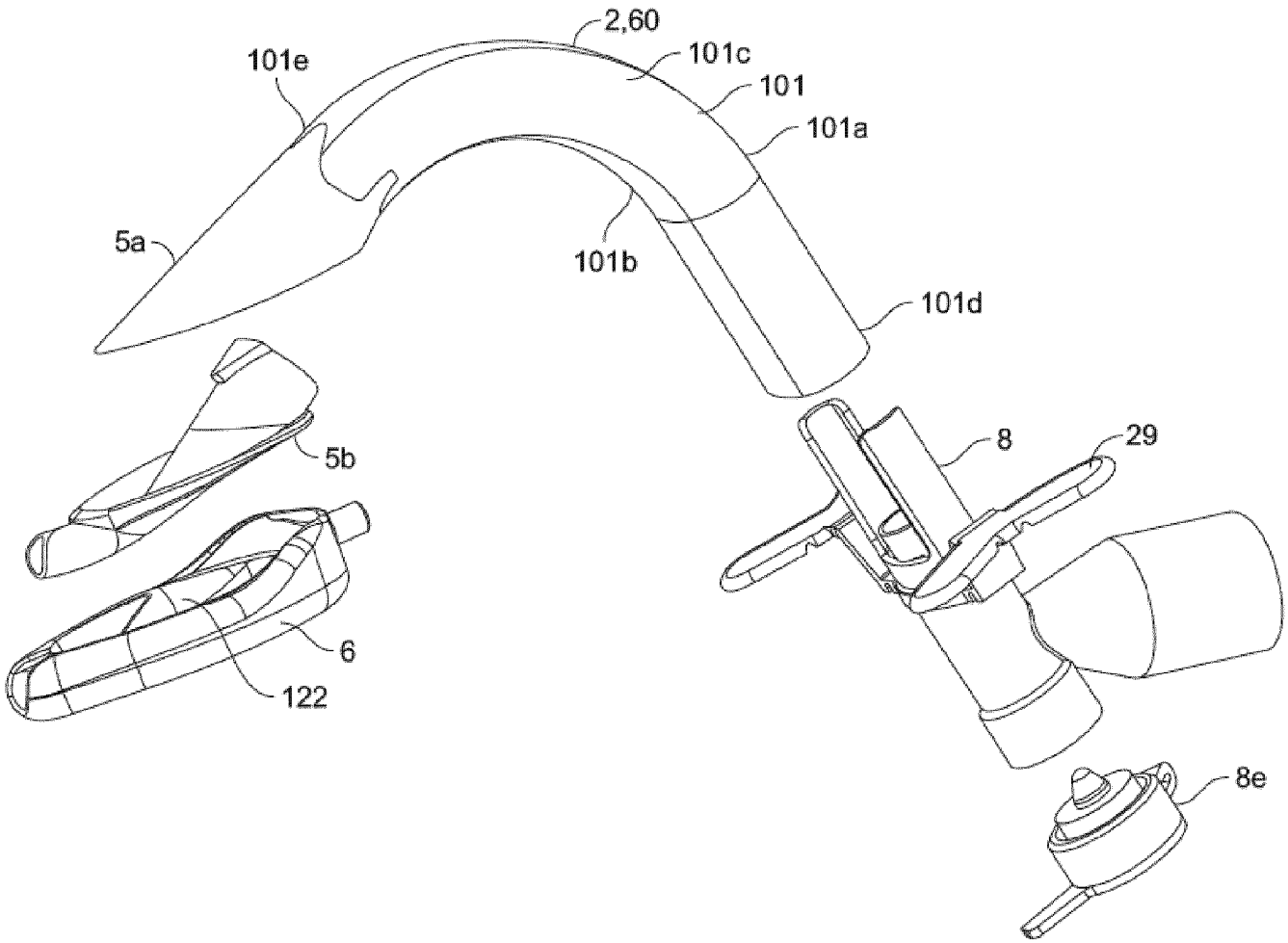


FIG. 6

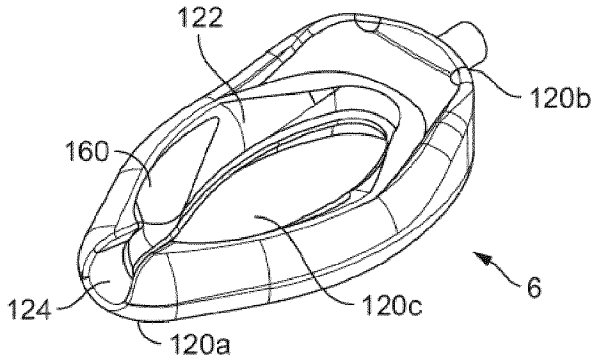


FIG. 7a

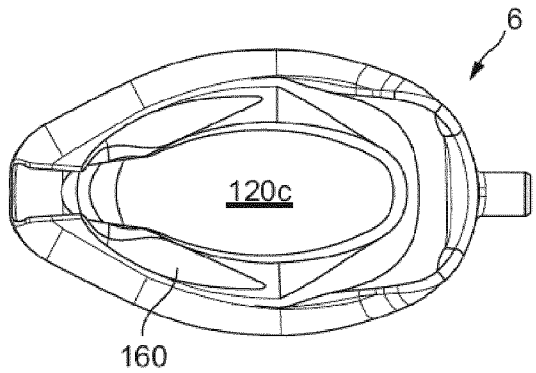


FIG. 7b

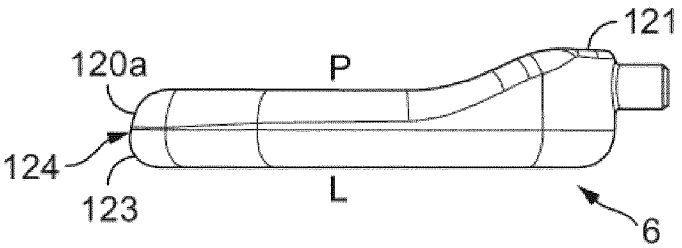


FIG. 7c

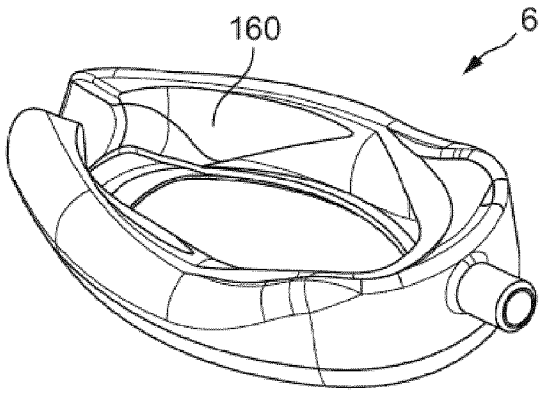


FIG. 7d

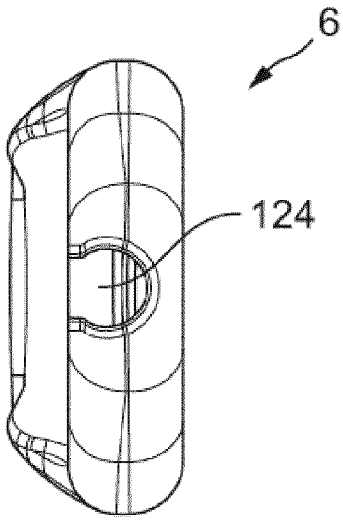


FIG. 7e

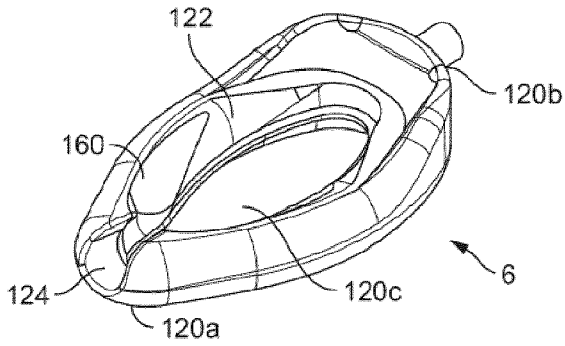


FIG. 7a

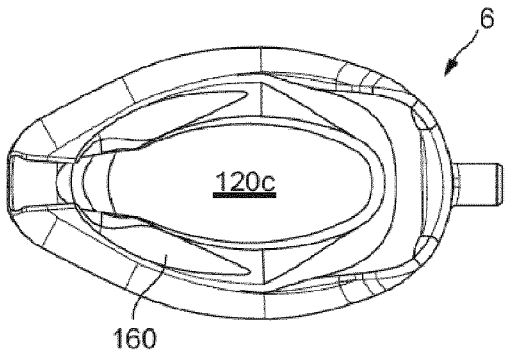


FIG. 7b

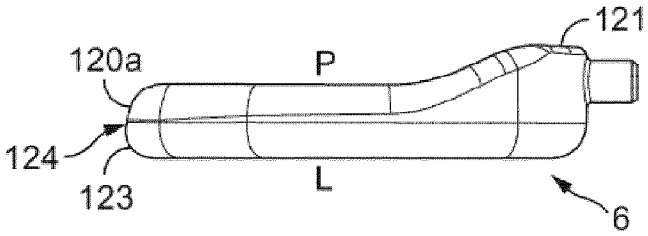


FIG. 7c

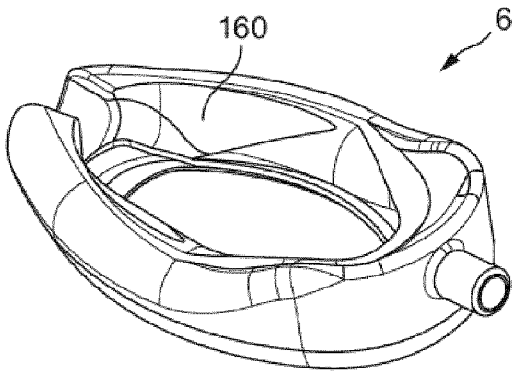


FIG. 7d

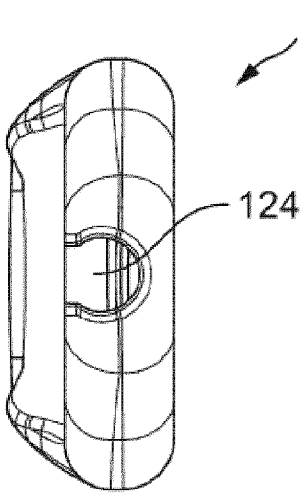


FIG. 7e

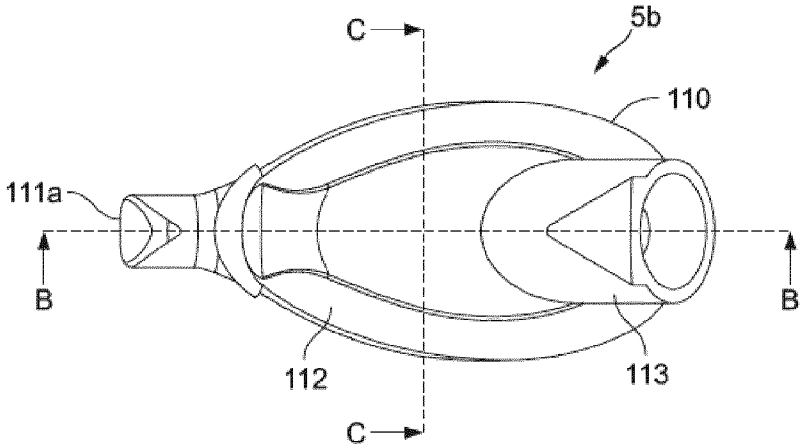
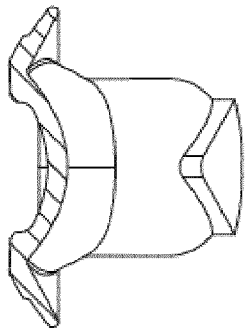
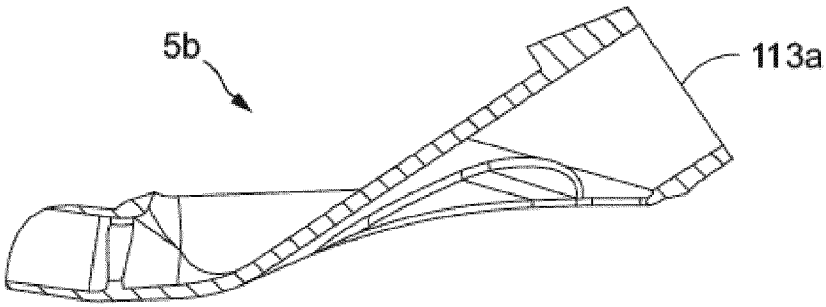


FIG. 8a



SECTION C-C

FIG. 8b



SECTION B-B

FIG. 8c

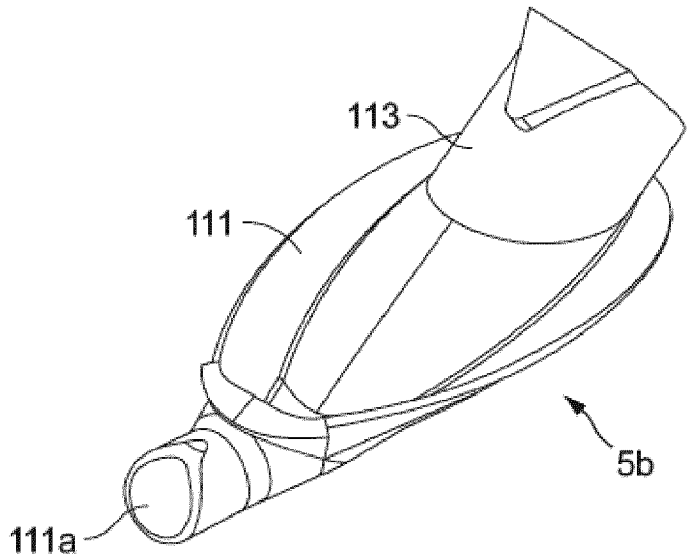


FIG. 8d

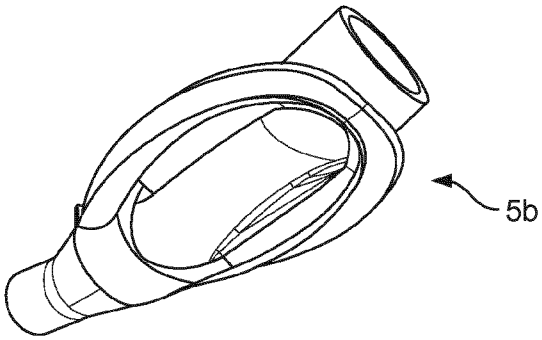


FIG. 9

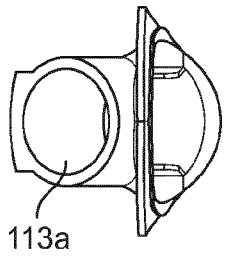


FIG. 10

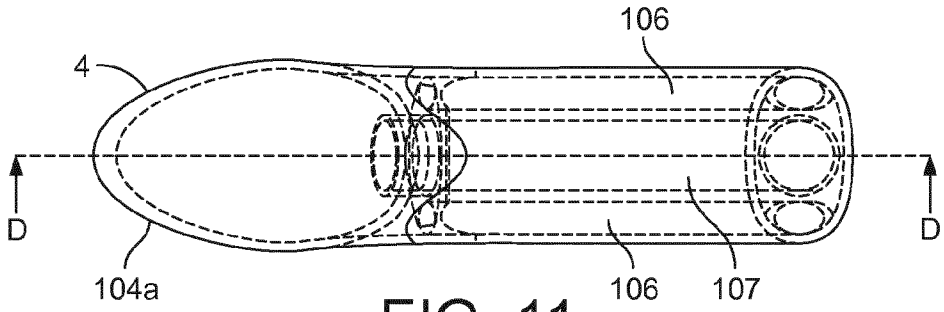
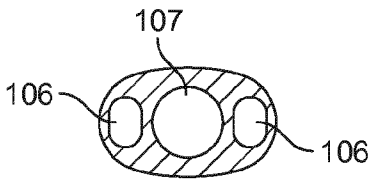
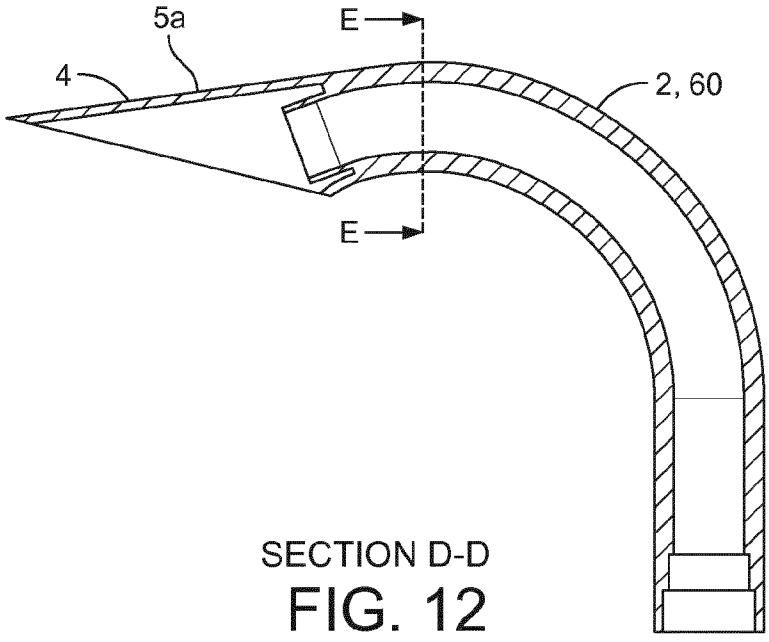


FIG. 11



SECTION E-E

FIG. 13



SECTION D-D

FIG. 12

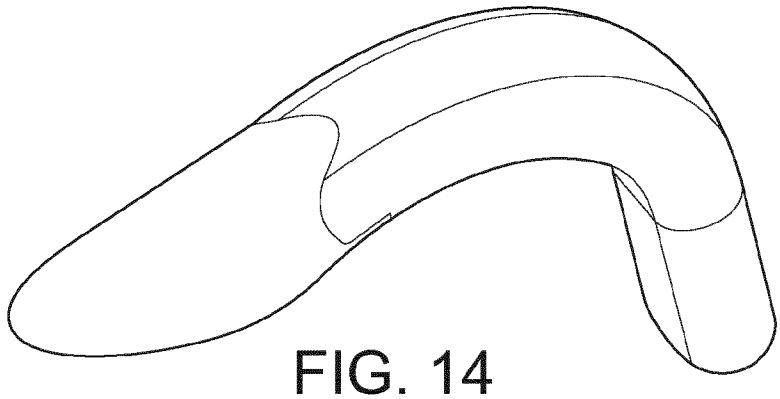


FIG. 14

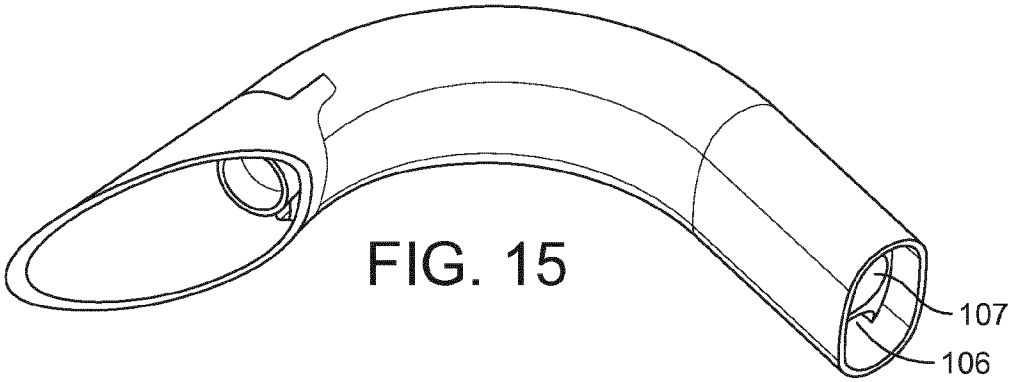


FIG. 15

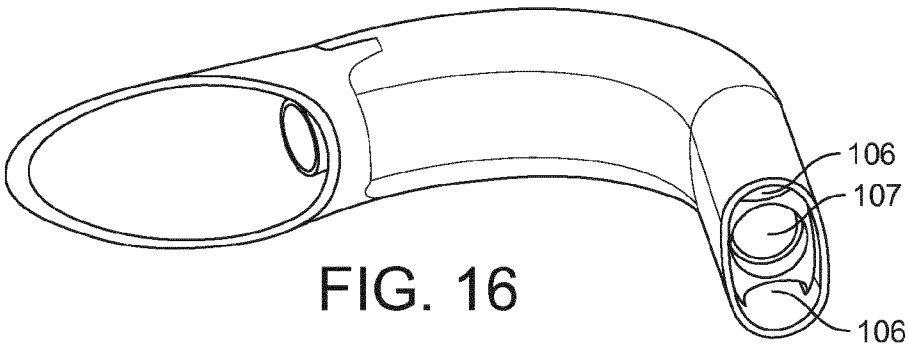


FIG. 16

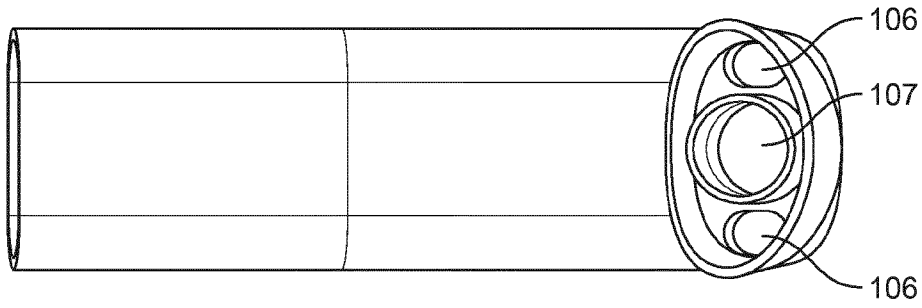


FIG. 16a

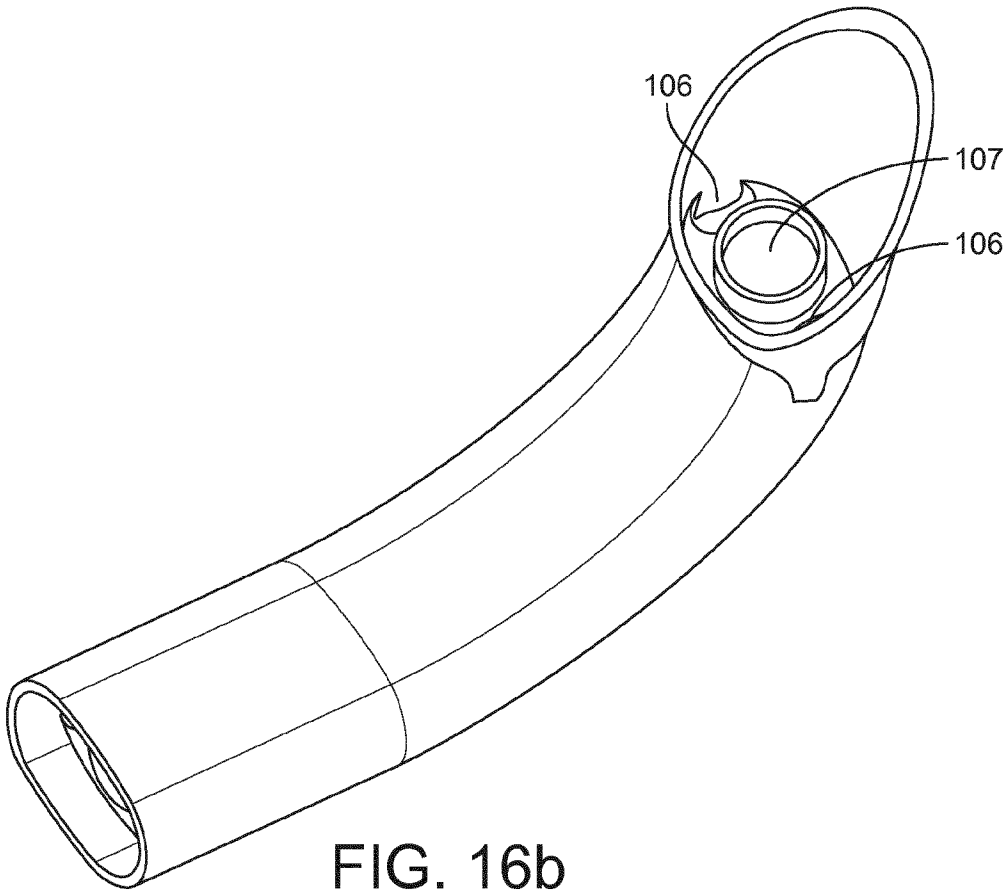


FIG. 16b

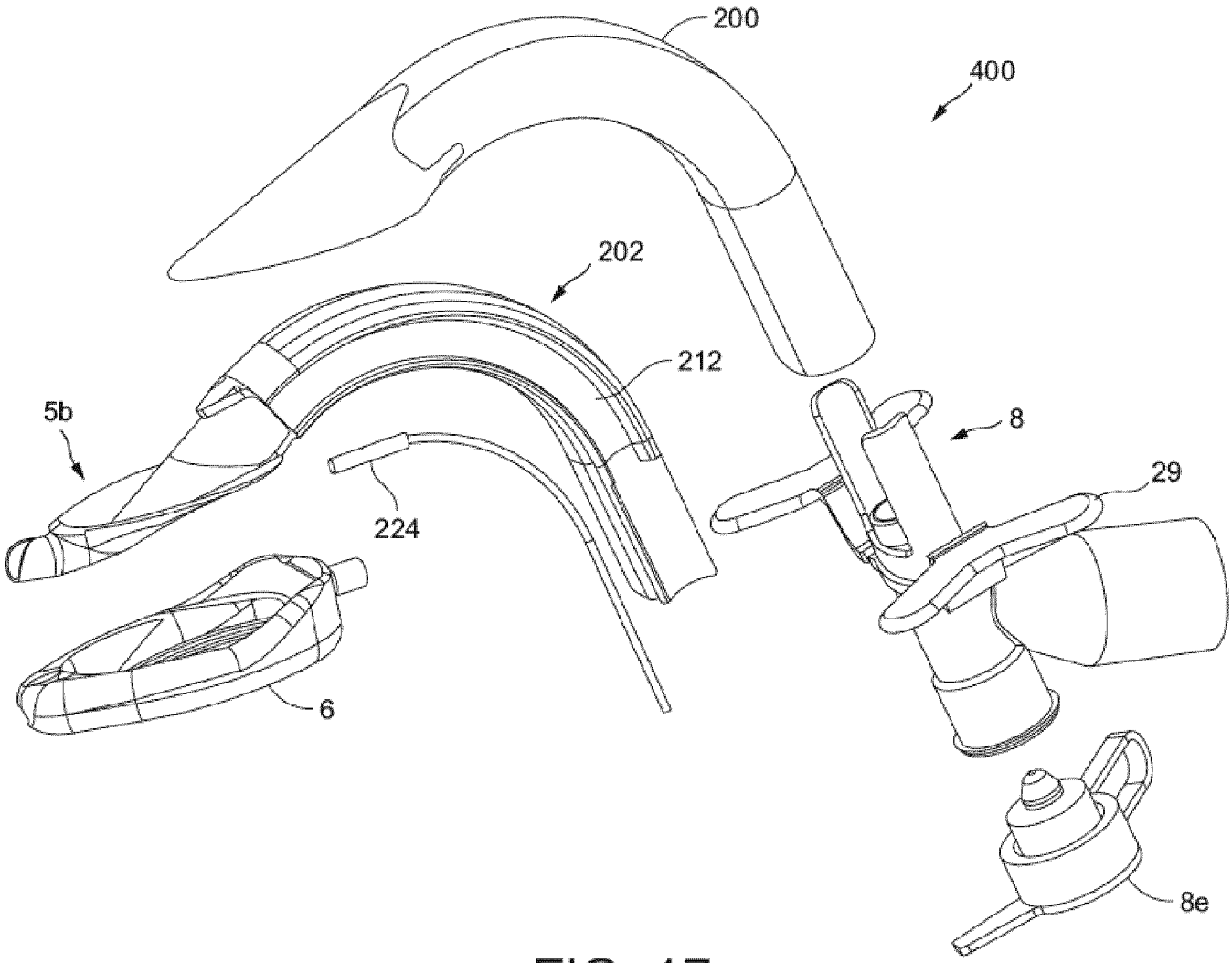


FIG. 17

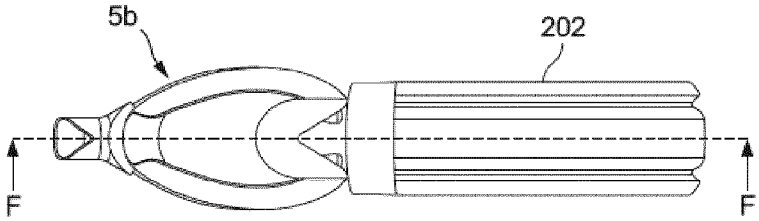
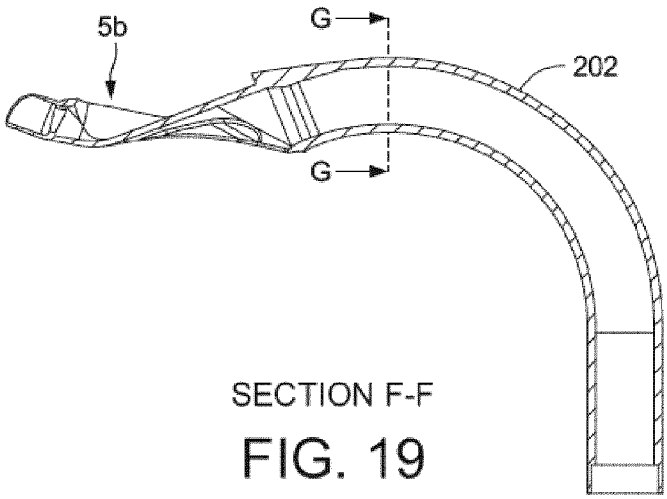
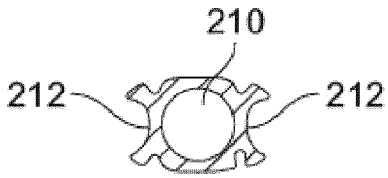


FIG. 18



SECTION F-F

FIG. 19



SECTION G-G

FIG. 20

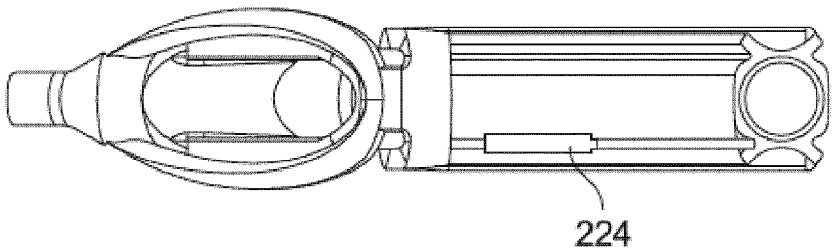


FIG. 21

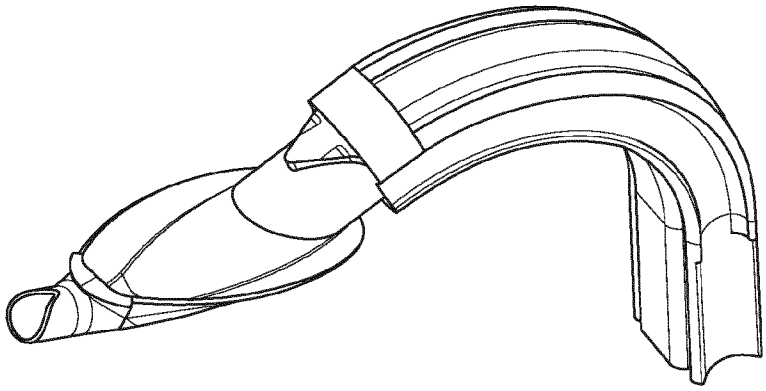


FIG. 22

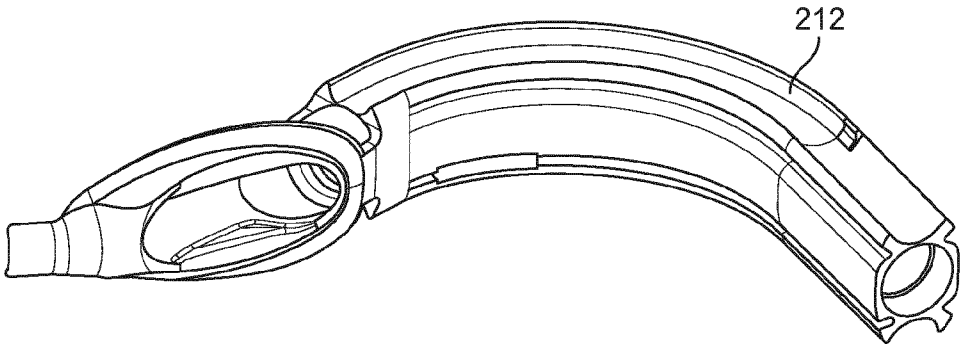


FIG. 23

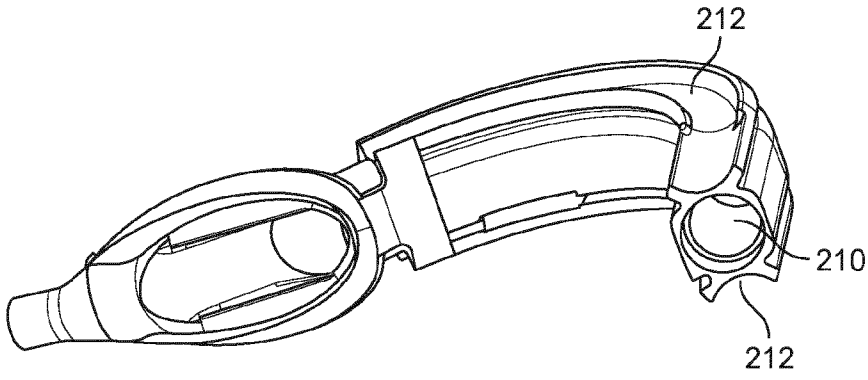


FIG. 24

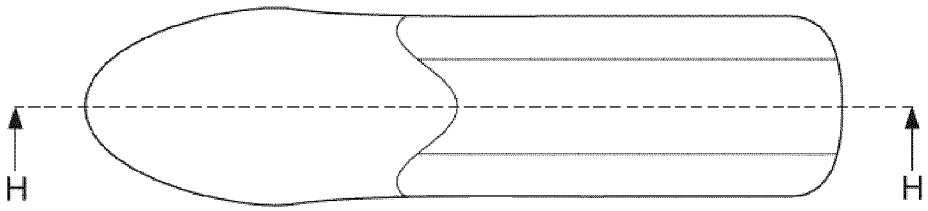
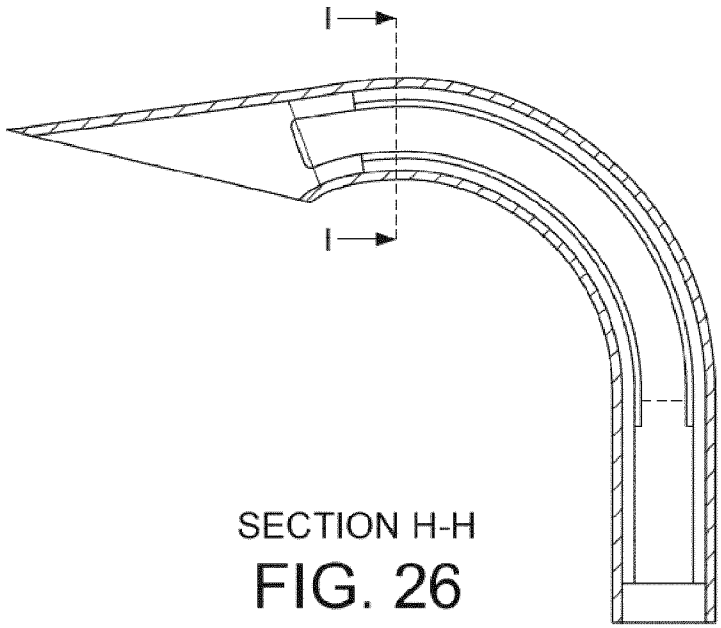


FIG. 25



SECTION H-H

FIG. 26

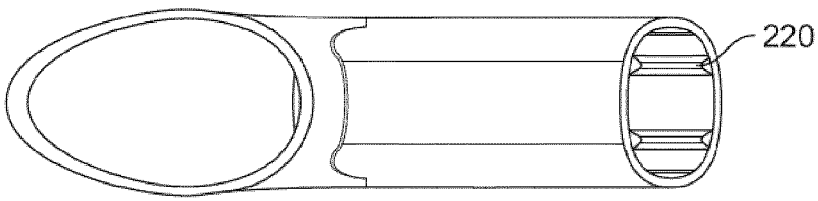
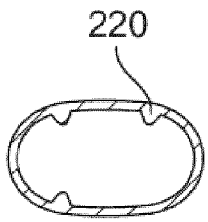


FIG. 27



SECTION I-I

FIG. 28

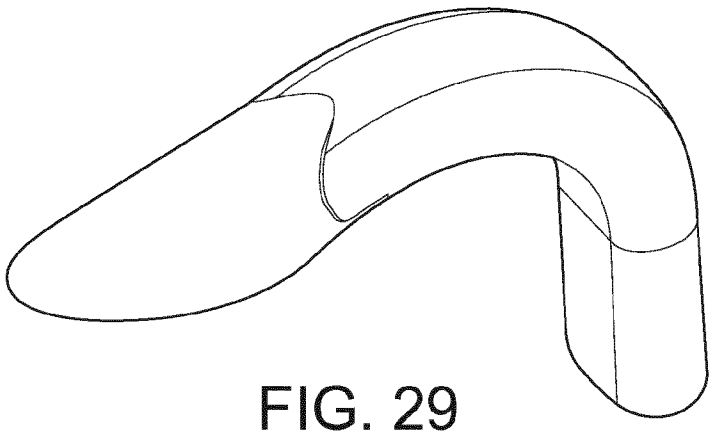


FIG. 29

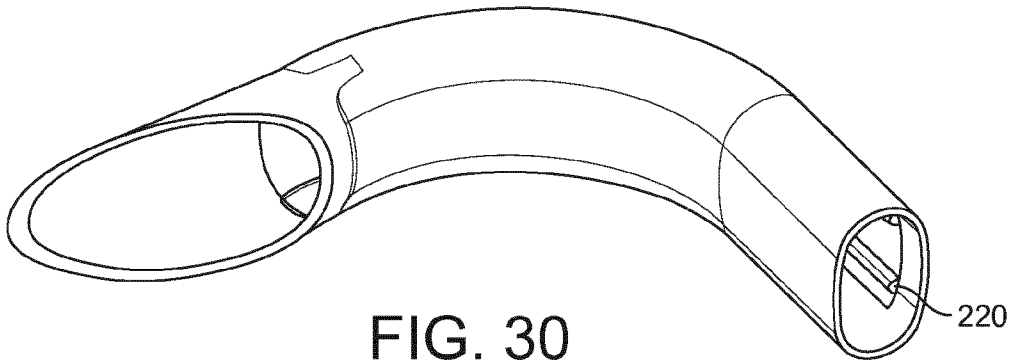


FIG. 30

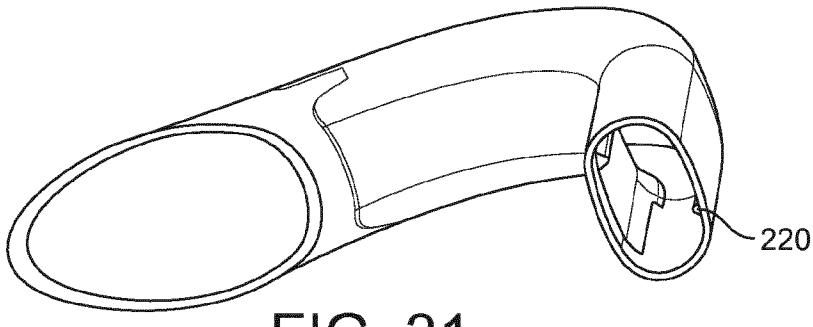


FIG. 31

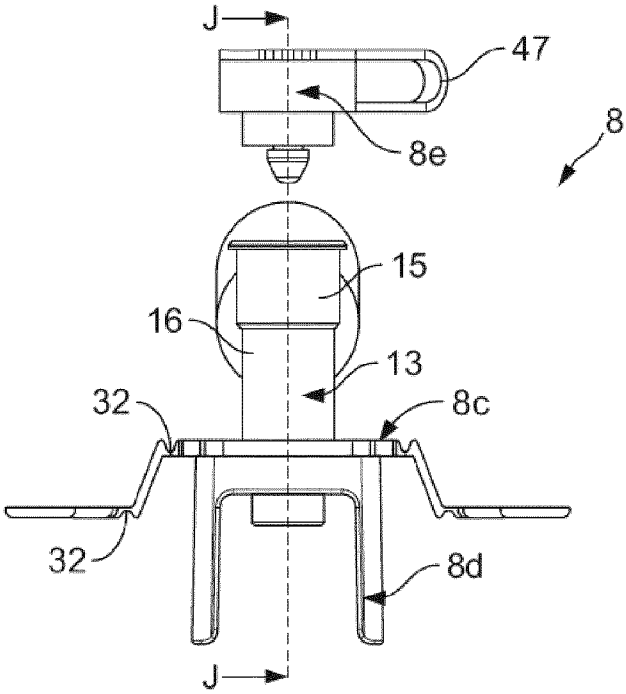
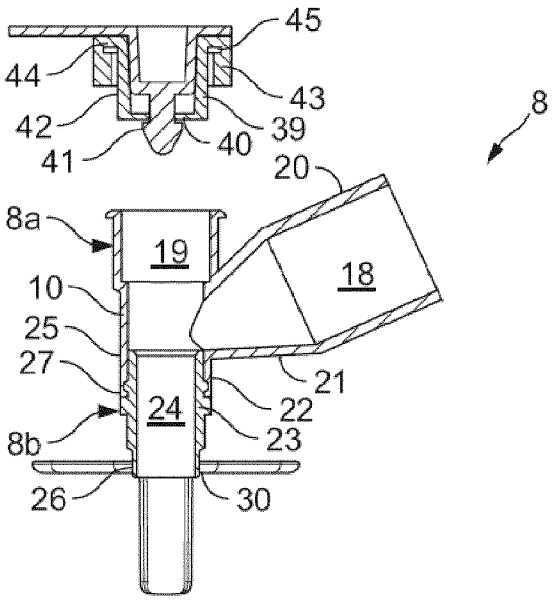


FIG. 32



SECTION J-J

FIG. 33

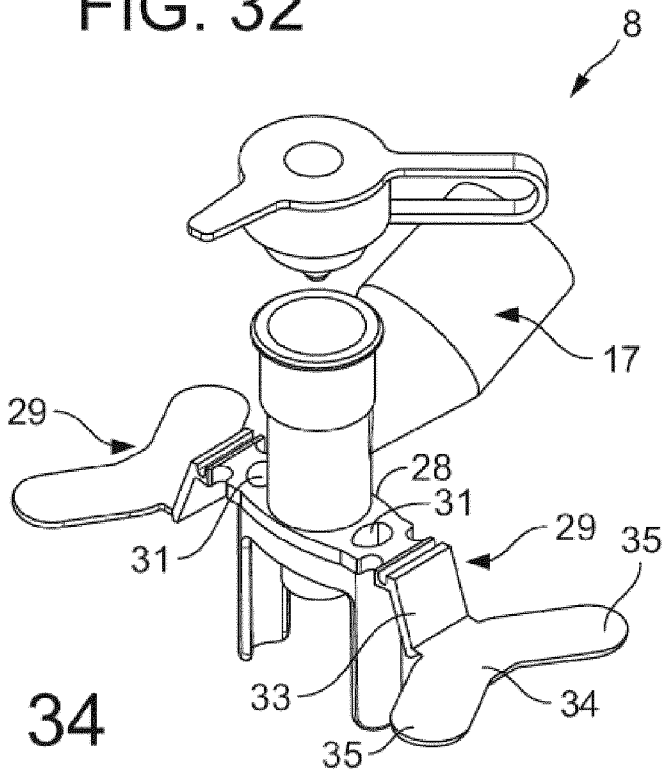


FIG. 34

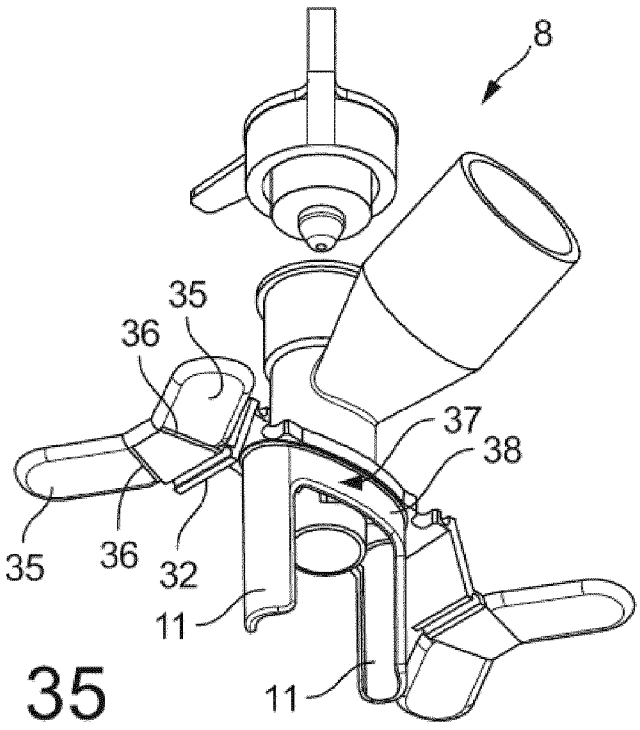


FIG. 35

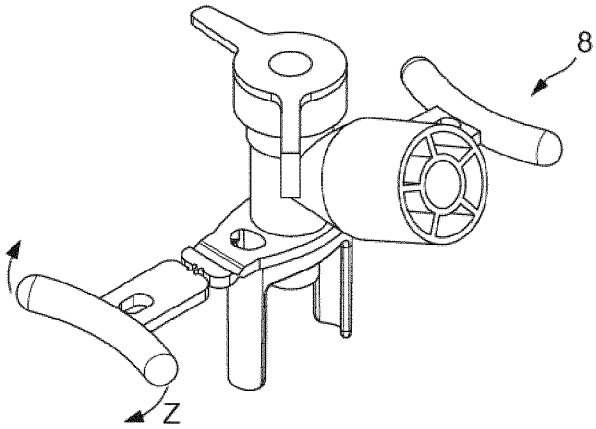


FIG. 36

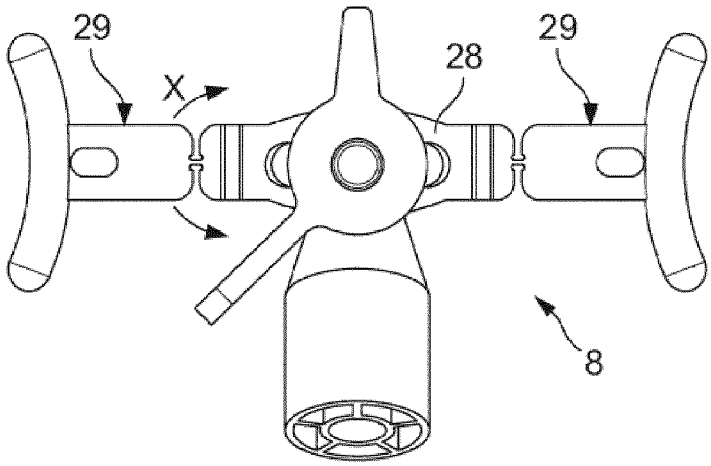


FIG. 37

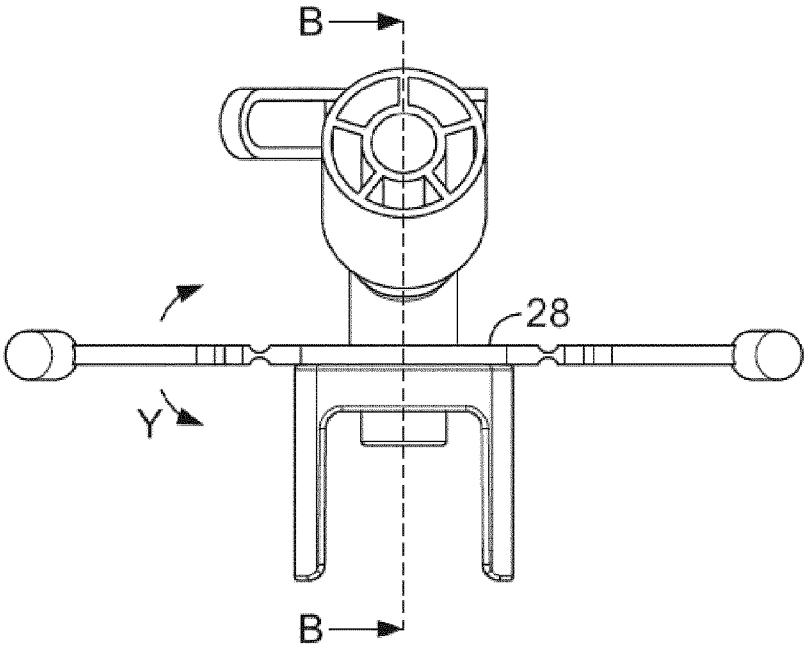
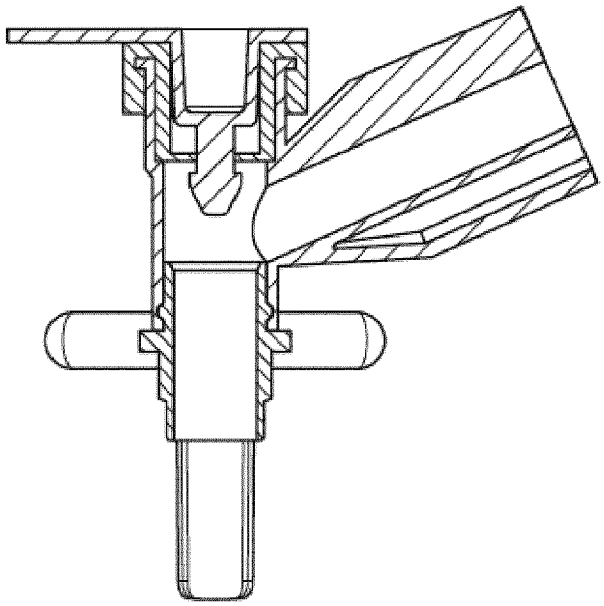


FIG. 38



SECTION B-B

FIG. 39

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/076918

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
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 A	GB 2 454 199 A (LARYNGEAL MASK CO LTD [SC]) 6 May 2009 (2009-05-06) abstract; figures 1a, 1c page 8, line 31 - page 14, line 18	1-17,19, 20,26-32 18,21-25
A	EP 1 663 364 B1 (BRAIN ARCHIBALD IAN JEREMY [SC]; LARYNGEAL MASK CO LTD [SC]) 14 April 2010 (2010-04-14) cited in the application the whole document	1-32
A	WO 2012/049448 A2 (LARYNGEAL MASK CO LTD [SC]; BRAIN ARCHIBALD IAN JEREMY [SC]) 19 April 2012 (2012-04-19) the whole document	1-32
A	WO 02/40079 A2 (EVERGREEN MEDICAL INC [US]) 23 May 2002 (2002-05-23) the whole document	1-32

☐ Further documents are listed in the continuation of Box C.

☒ 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
22 January 2018	31/01/2018

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

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/076918

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.: 33
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.

Continuation of Box II.1

Claims Nos.: 33

Methods of providing ventilation to a subject as defined in claim 33 of the present application are methods for treatment of human or animal body by therapy. Indeed these methods are meant to ventilate the lung of a patient (see page 5). Thus, claim 33 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/EP2017/076918

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