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(54) **DEVICE FOR SURFACTANT ADMINISTRATION AND VENTILATION OF LOW BIRTH WEIGHT INFANTS**

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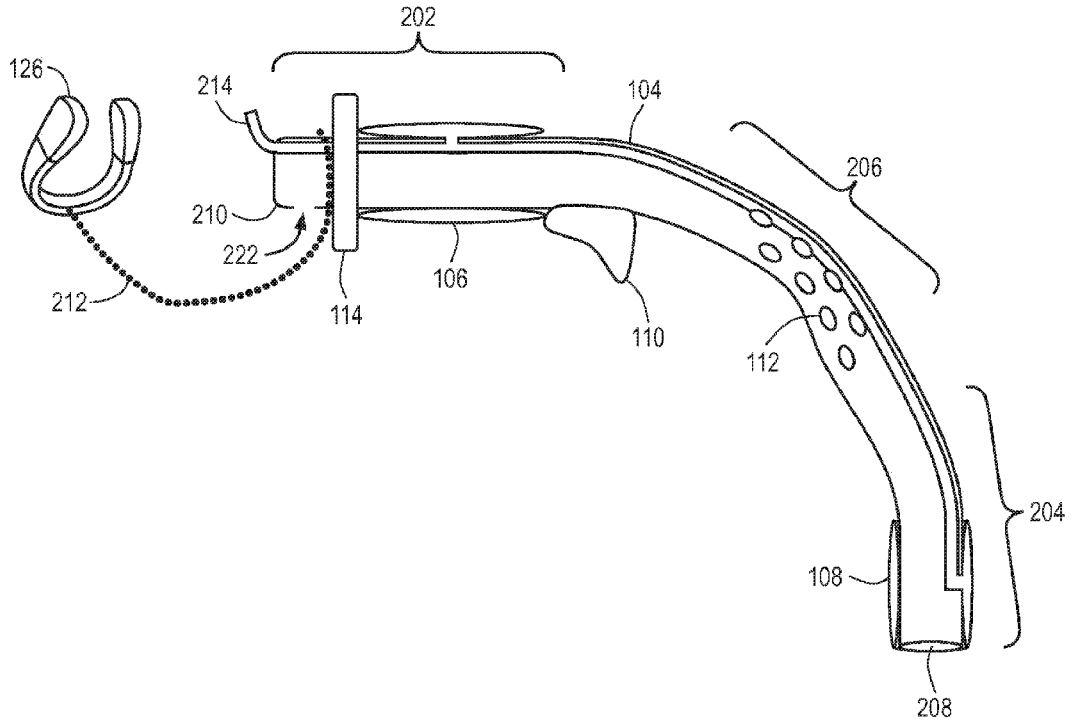
(57) **ABSTRACT**

A fluid delivery and airway management device including a tubular member dimensioned for introducing a fluid into a trachea of a mammal, the tubular member having a proximal portion, a distal portion, and a middle portion between the proximal portion and the distal portion. The tubular member is dimensioned for positioning of the proximal portion in an oral cavity of a mammal, the middle portion in an oropharynx of the mammal and the distal portion in an esophagus of the mammal. An inflatable oral cavity balloon is positioned at the proximal portion and dimensioned to occlude the oral cavity. An inflatable esophageal balloon is positioned at the distal portion and dimensioned to occlude the esophagus. Apertures may he formed within the middle portion such that a fluid introduced into the tubular member is output through the apertures to a trachea.



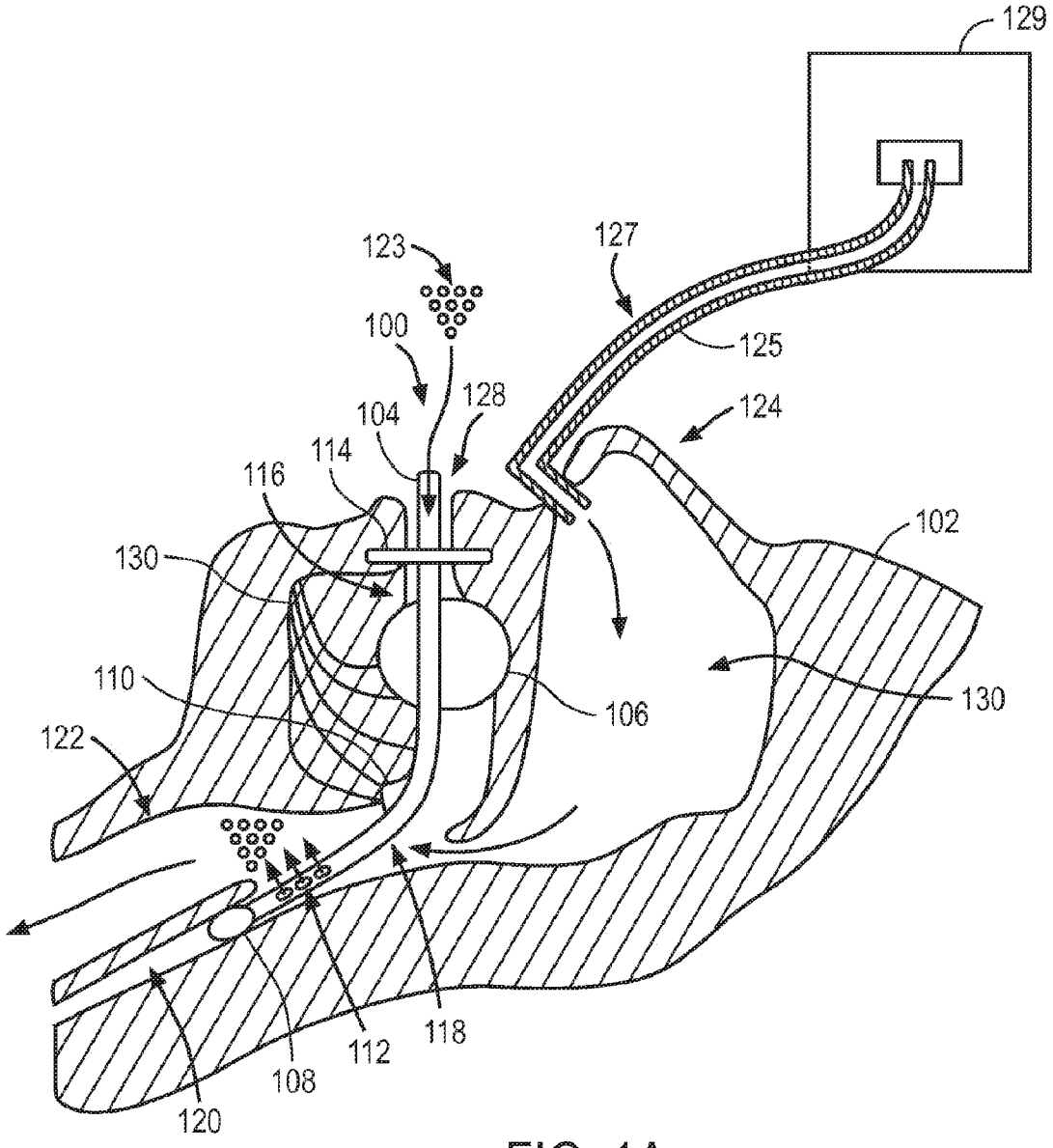

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FIG. 1A

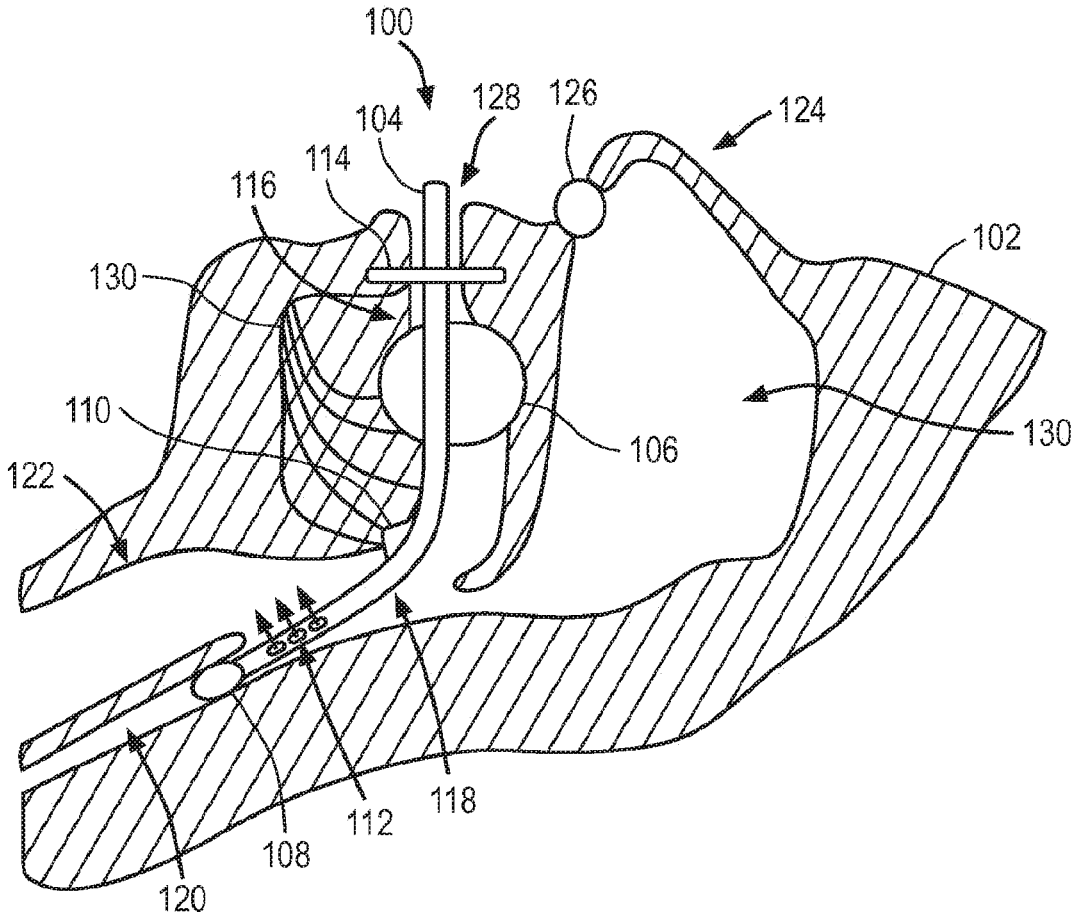
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FIG. 1B

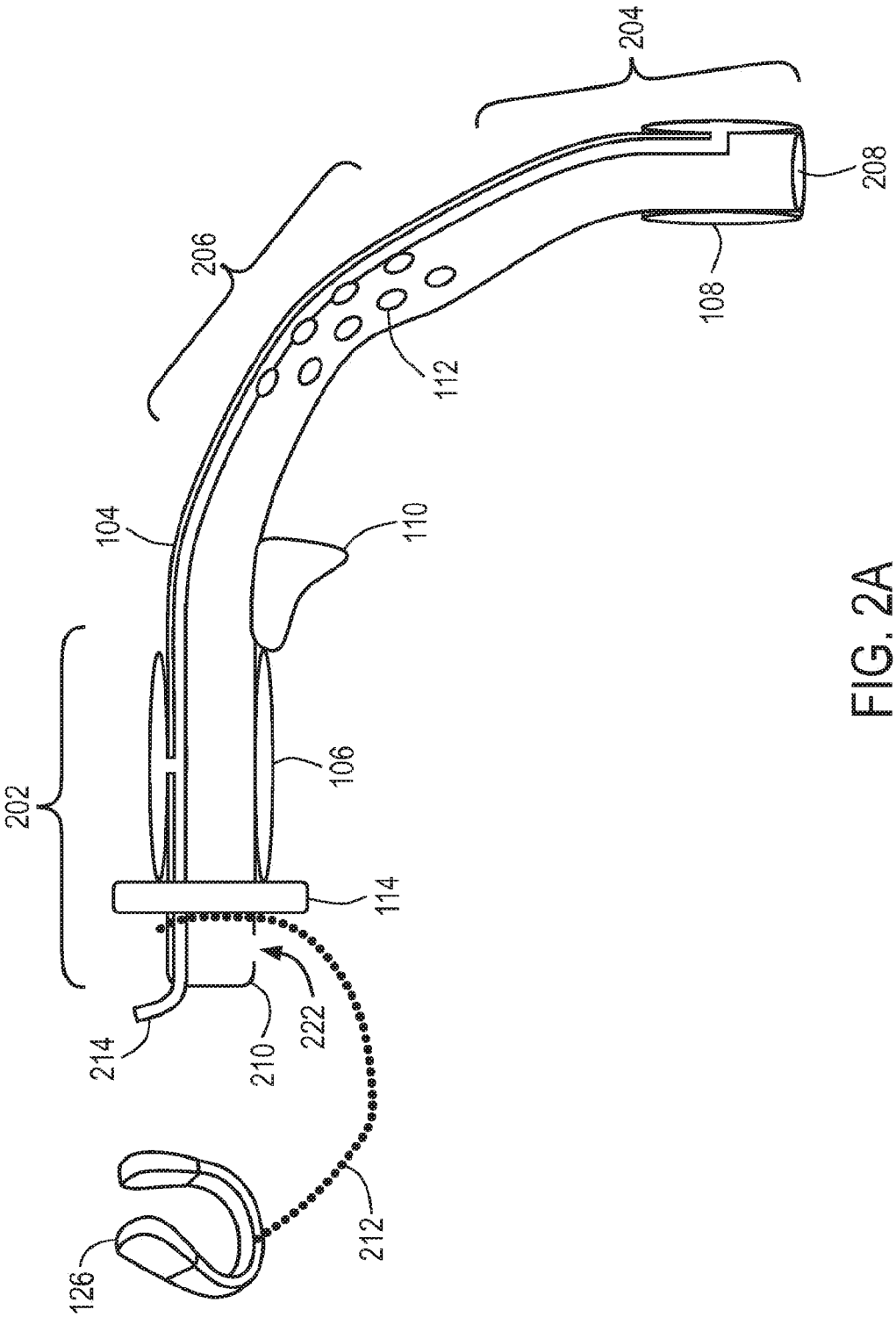

FIG. 2A

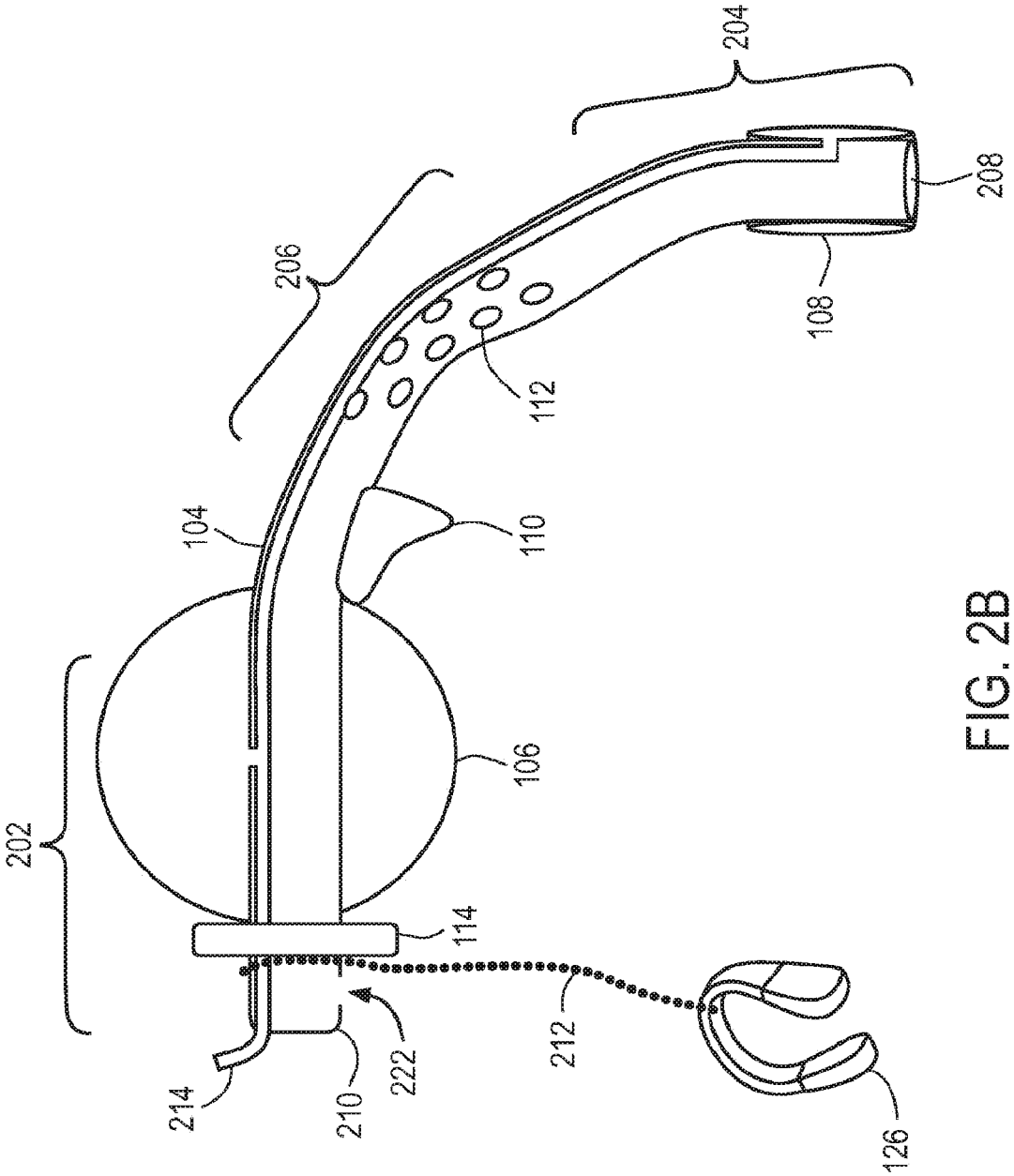

FIG. 2B

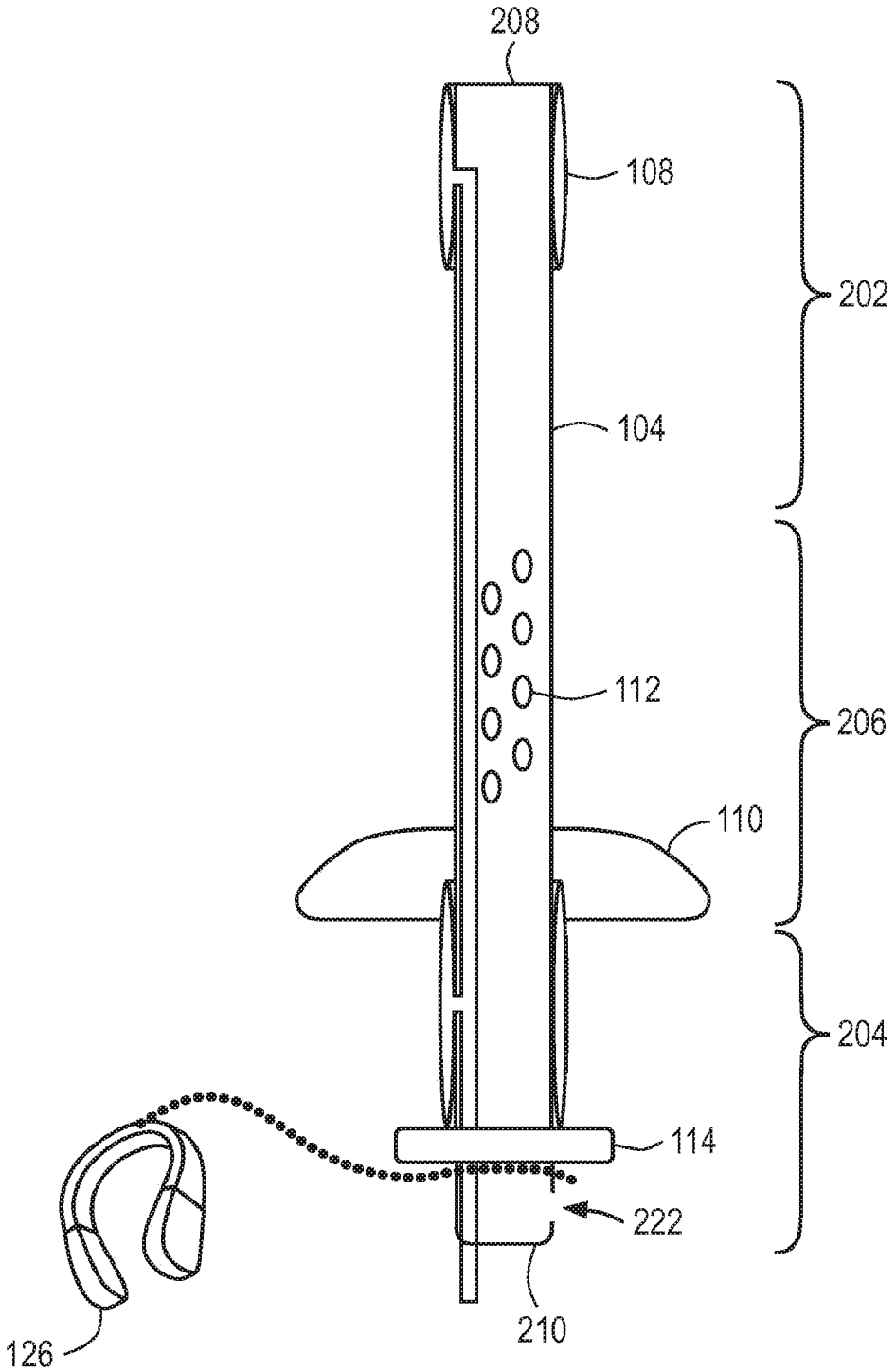

FIG. 3A

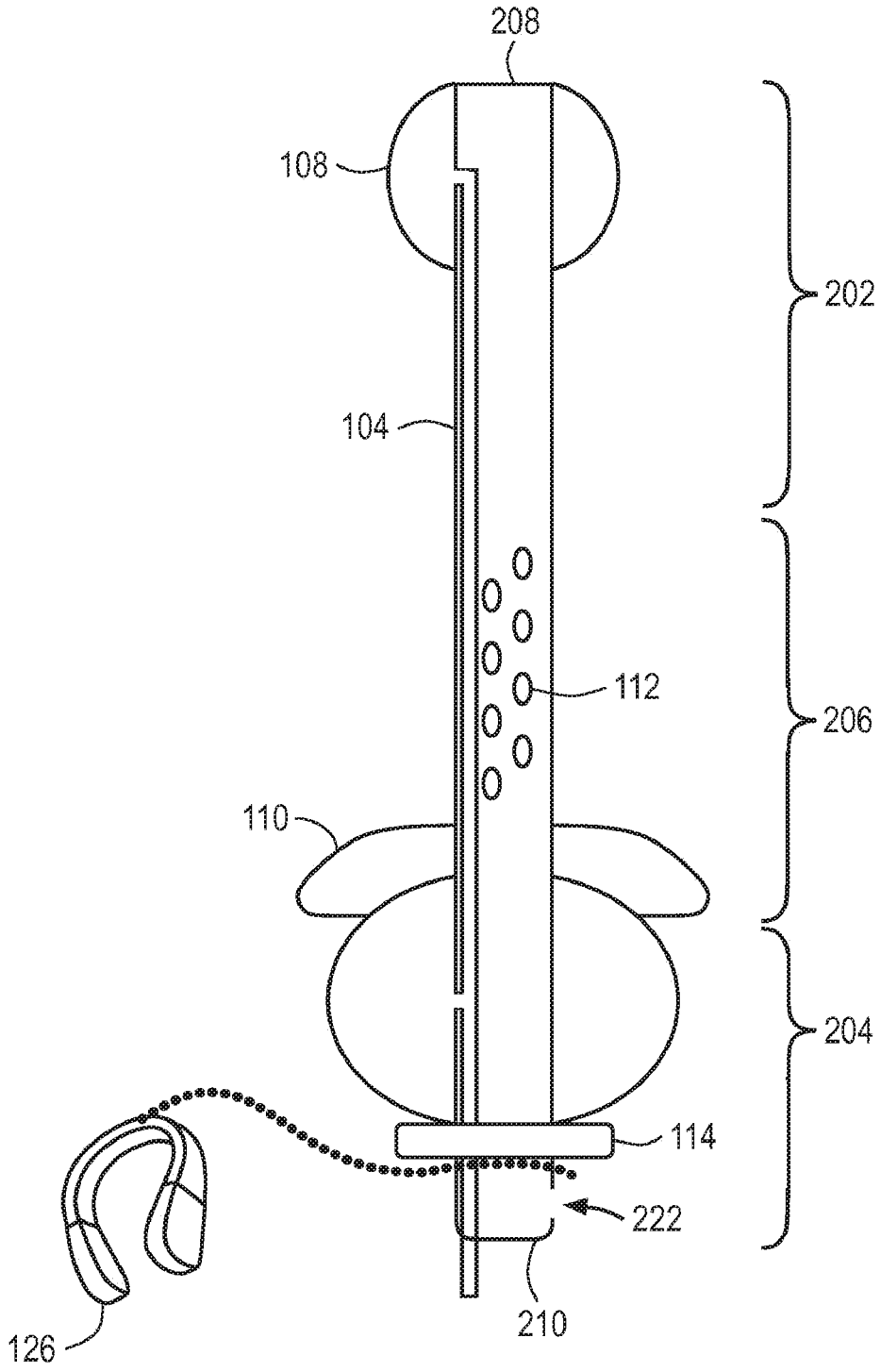

FIG. 3B

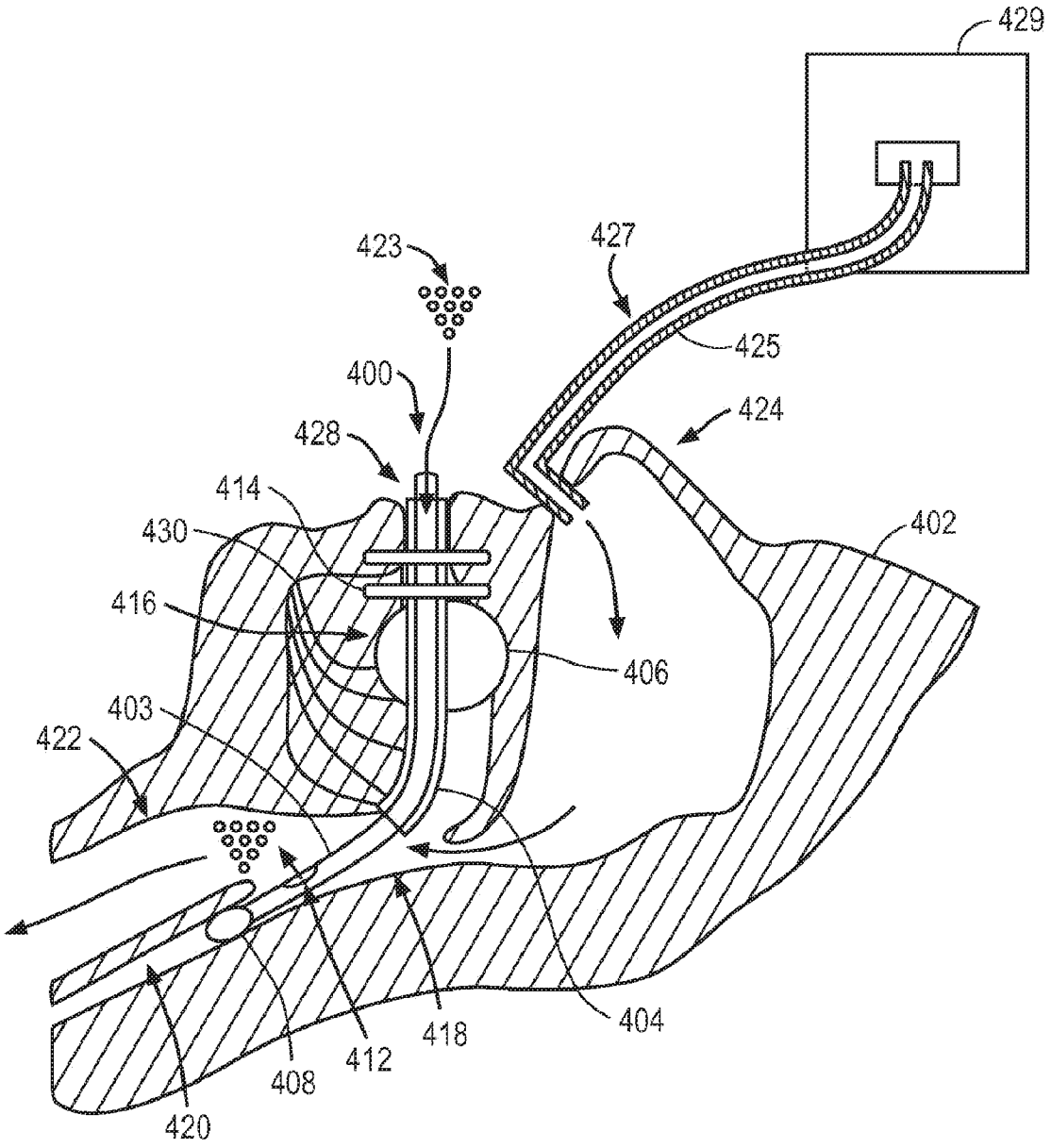
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FIG. 4A

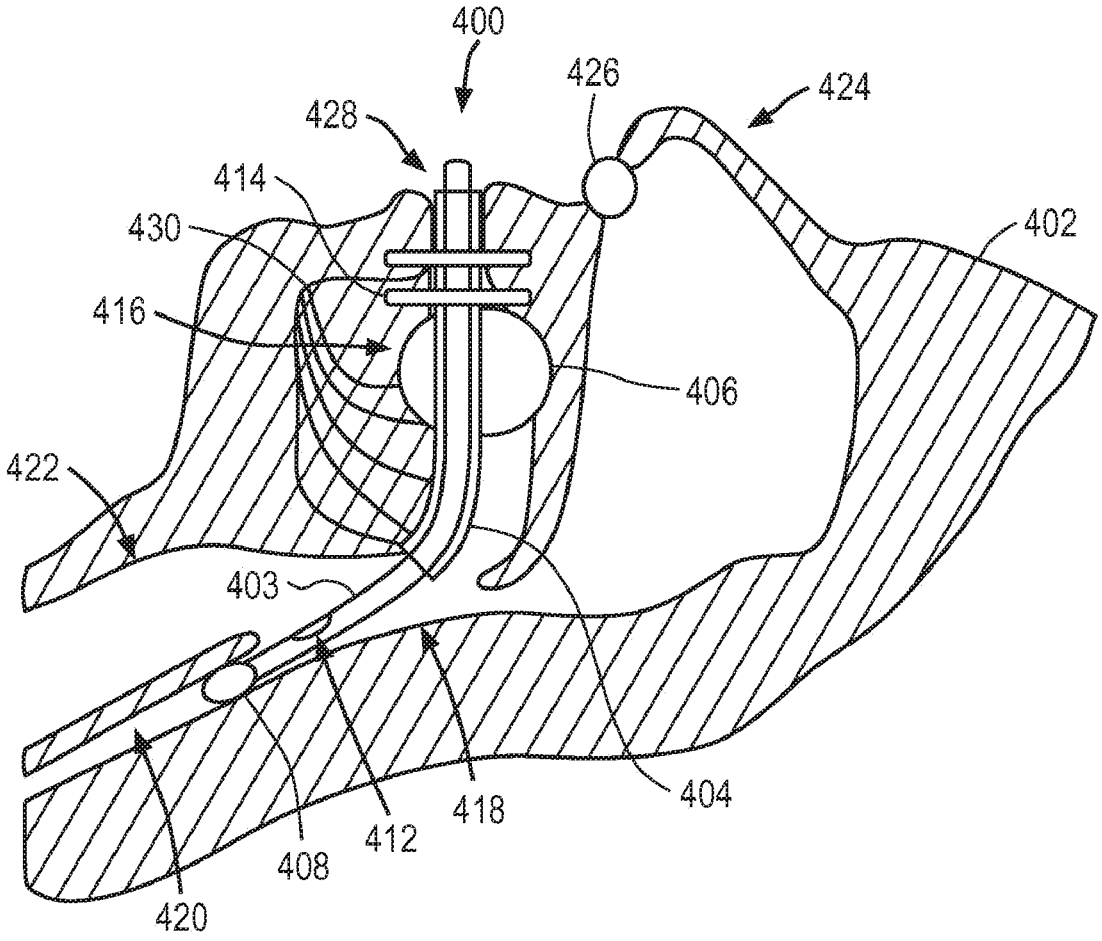

FIG. 4B

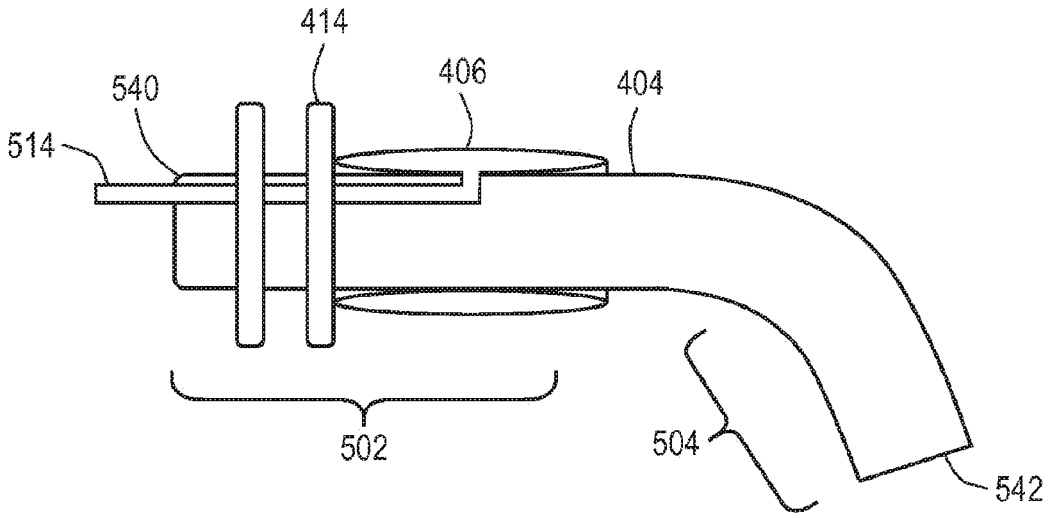

FIG. 5A

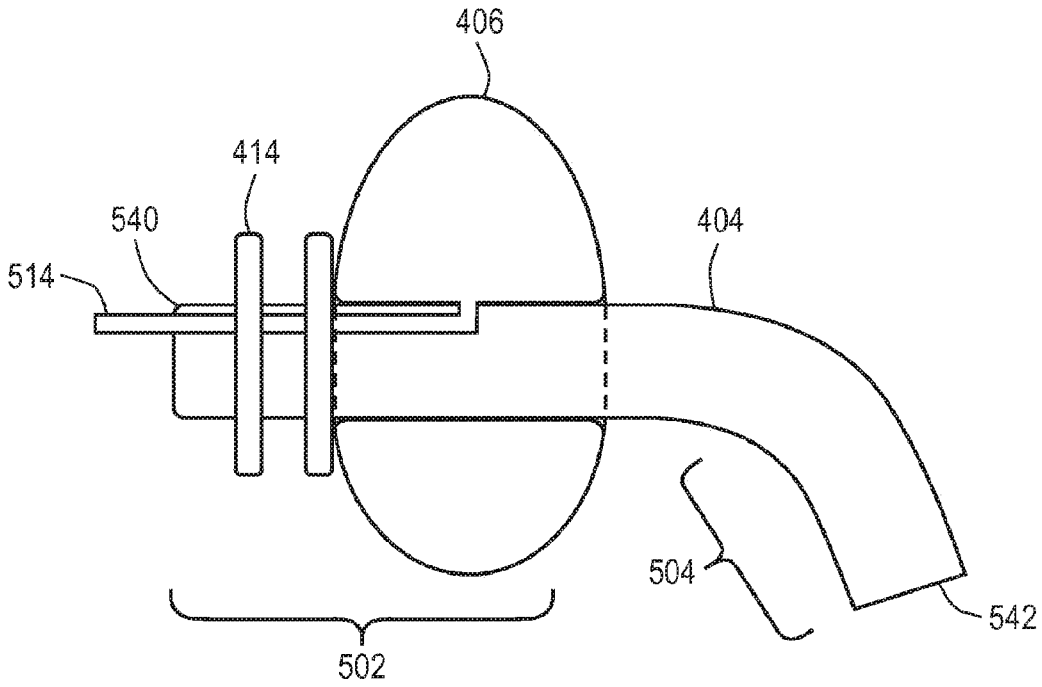

FIG. 5B

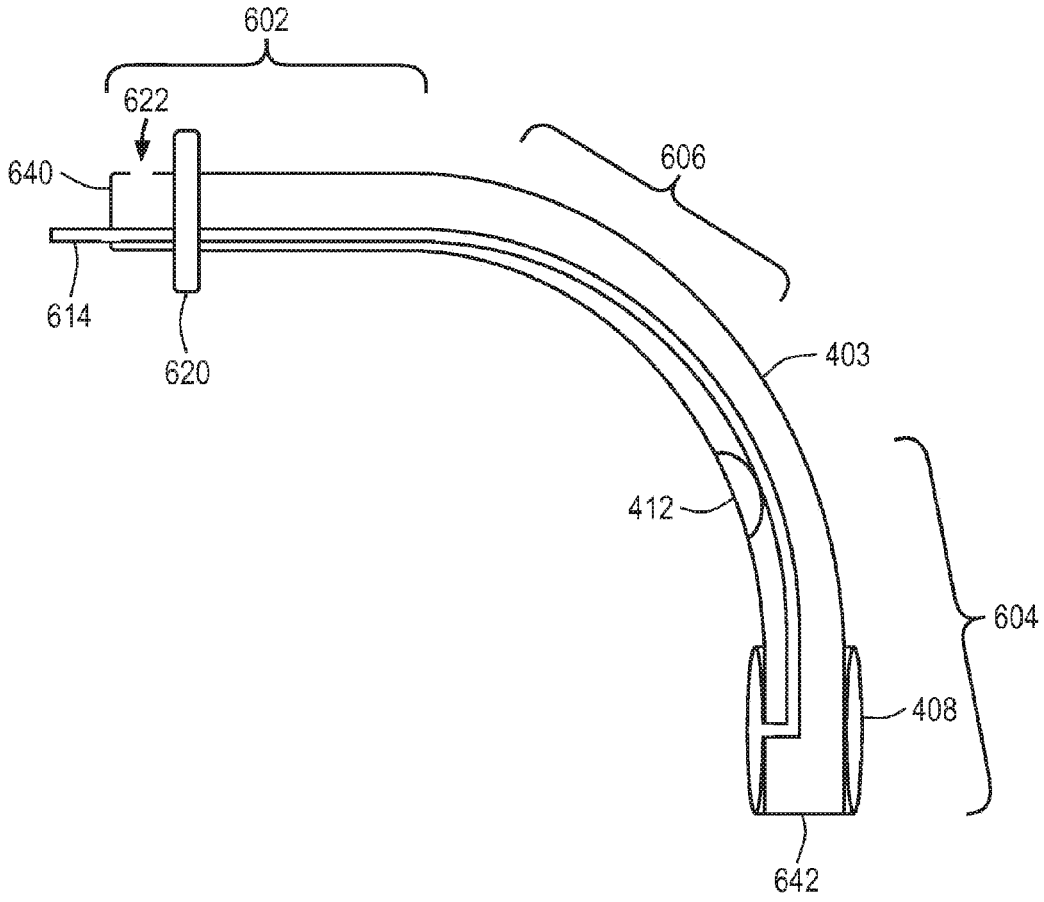

FIG. 6A

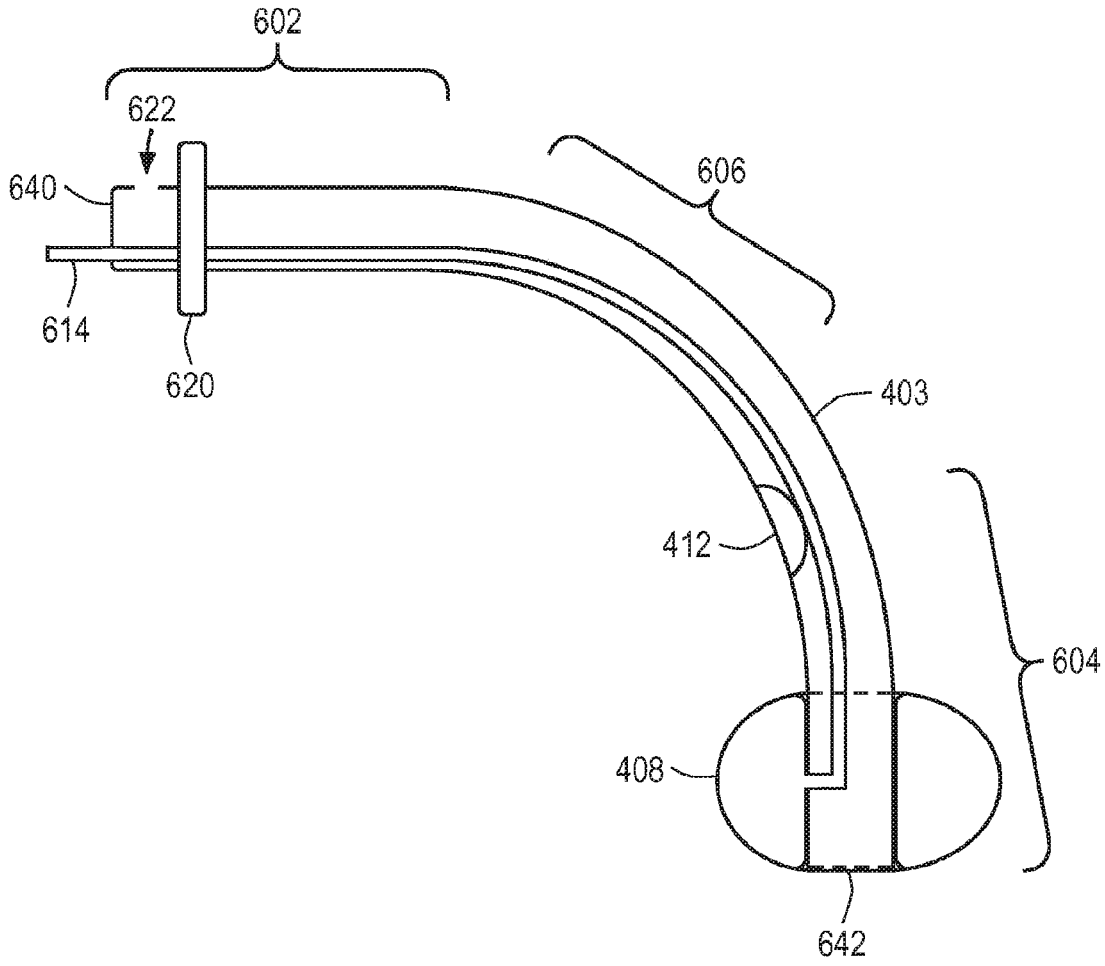

FIG. 6B

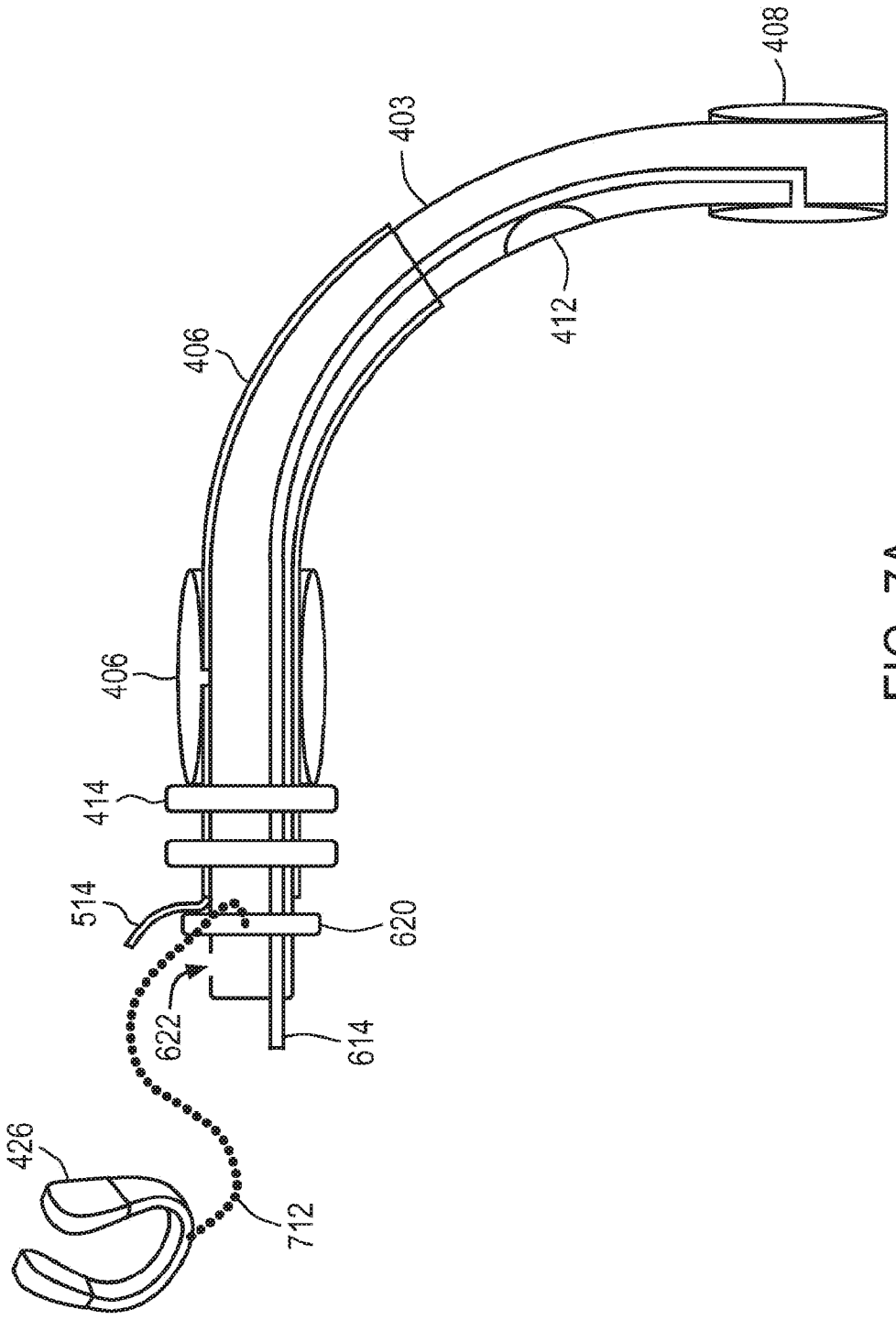

FIG. 7A

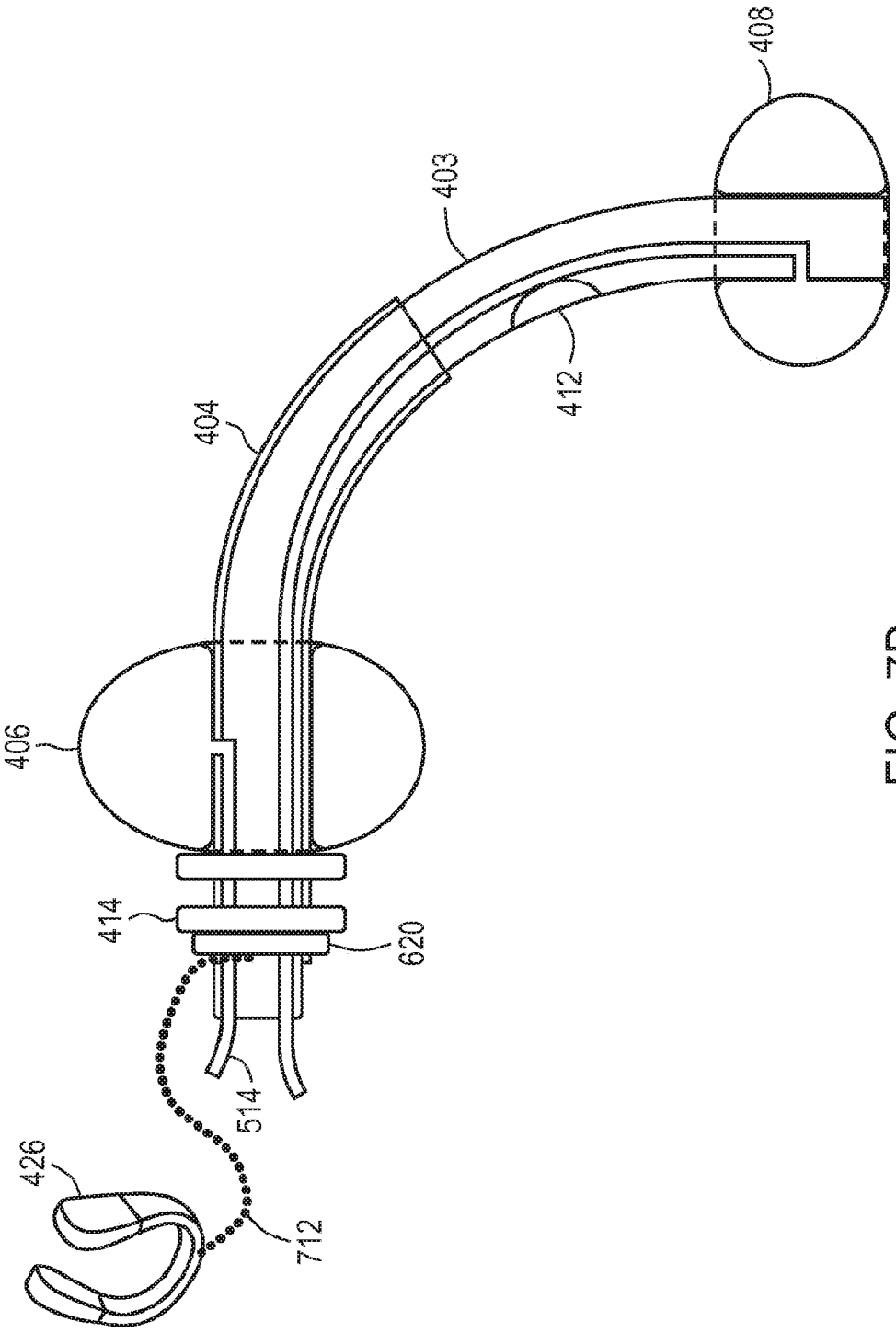

FIG. 7B

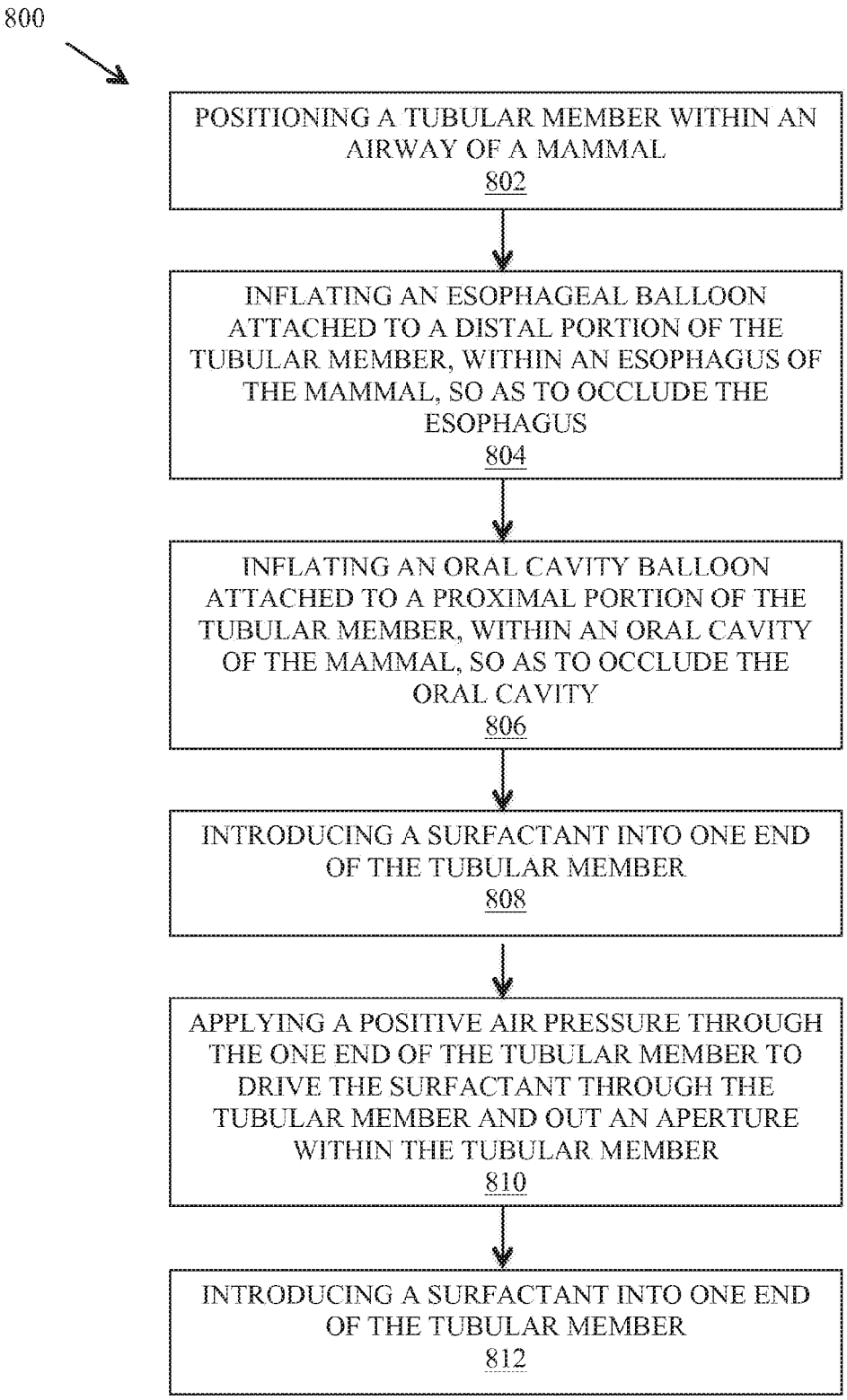
800
POSITIONING A TUBULAR MEMBER WITHIN AN AIRWAY OF A MAMMAL
802
INFLATING AN ESOPHAGEAL BALLOON ATTACHED TO A DISTAL PORTION OF THE TUBULAR MEMBER, WITHIN AN ESOPHAGUS OF THE MAMMAL, SO AS TO OCCLUDE THE ESOPHAGUS
804
INFLATING AN ORAL CAVITY BALLOON ATTACHED TO A PROXIMAL PORTION OF THE TUBULAR MEMBER, WITHIN AN ORAL CAVITY OF THE MAMMAL, SO AS TO OCCLUDE THE ORAL CAVITY
806
INTRODUCING A SURFACTANT INTO ONE END OF THE TUBULAR MEMBER
808
APPLYING A POSITIVE AIR PRESSURE THROUGH THE ONE END OF THE TUBULAR MEMBER TO DRIVE THE SURFACTANT THROUGH THE TUBULAR MEMBER AND OUT AN APERTURE WITHIN THE TUBULAR MEMBER
810
INTRODUCING A SURFACTANT INTO ONE END OF THE TUBULAR MEMBER
812

FIG. 8

DEVICE FOR SURFACTANT ADMINISTRATION AND VENTILATION OF LOW BIRTH WEIGHT INFANTS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority from U.S. Provisional Patent Application Ser. No. 61/847,232, filed on Jul. 17, 2013.

FIELD

[0002] A device, kit and method for fluid delivery and/or airway management of a patient, more specifically, a device for surfactant delivery and ventilation of premature or otherwise very low birth weight infants. Other embodiments are also described herein.

BACKGROUND

[0003] Many preterm infants suffer from respiratory distress syndrome (RDS) which can be caused by insufficient surfactant production and structural immaturity in the lungs, Such infants may therefore require surfactant replacement therapy. Surfactant replacement therapy refers to the administration of a surfactant to the infant's lungs and has been found to reduce mortality and morbidity rates in premature infants, reduce duration of ventilatory support, number of complications and medical costs. The surfactant is typically in liquid form and may be synthetic or animal derived.

[0004] The current standard practice of surfactant administration is to first intubate the premature infant with an endotracheal tube. The infant is then administered the surfactant in liquid form via the endotracheal tube. Next, the infant is extubated and subjected to nasal continuous positive air pressure (CPAP) to help drive the surfactant into the lungs. If the infant fails nasal CPAP, then he/she will be intubated again to start on mechanical ventilation via the endotracheal tube. Intubation of small, premature infants with an endotracheal tube, however, is a difficult procedure and therefore requires a clinician with a high degree of skill. In addition, endotracheal intubation can cause complications such as vocal cord injury, tracheal perforation and airway trauma.

[0005] Some new surfactant administration approaches in experimental stages include administering the liquid surfactant or an aerosolized surfactant nasally via CPAP. The effectiveness of nasal administration via CPAP, however, has not been demonstrated. In addition, since the pathway from the nose to the lungs is not sealed, some surfactant will enter into the mouth or esophagus, thus requiring higher surfactant doses (and increased cost). Moreover, although aerosolized administration may be promising, such approach is still experimental and therefore its efficacy is also in question.

SUMMARY

[0006] The delivery method and device disclosed herein provides a secure, effective, and easily placed fluid (e.g. surfactant) administration and airway conduit for premature infants and other very low birth weight infants (VLBI) suffering from conditions such as respiratory distress syndrome (RDS). The device is designed to deliver a fluid such as a surfactant while the infant is receiving nasal CPAP support, and can also serve as a rescue airway when CPAP is not providing adequate ventilatory support. In this aspect, the airway device is configured to deliver surfactant, or air in cases where ventilator support is necessary, to the trachea without endotracheal intubation. Representatively, in one embodiment, the device includes a hollow tube dimensioned for insertion through the patient's mouth to the esophagus. An oral cavity balloon dimensioned to block the oral cavity is positioned at one end of the tube and an esophageal balloon dimensioned to block the esophagus is positioned at another, closed, end of the tube. Apertures are further provided in a side of the tube that is aligned with the oropharynx. In this aspect, when surfactant or air is delivered into the one end of the tube, it passes through the tube and out the apertures to the oropharynx. In the case of ventilatory support, a nose block may further be provided such that the only way for air pumped into the tube to go is out the apertures and to the trachea. In this aspect, the airway device allows for surfactant or air to be pumped directly into the trachea. Furthermore, the esophageal balloon prevents reflux of gastric content from causing aspiration. In addition, positioning of the oral cavity balloon in oral cavity, instead of the oropharynx, avoids compression of vital structures (nerve plexus, venous sinuses and carotid arteries).

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The following illustration is by way of example and not by way of limitation in the figures of the accompanying drawings in which like references indicate like elements. It should be noted that references to "an" or "one" embodiment in this disclosure are not necessarily to the same embodiment, and such references mean at least one.

[0008] FIG. **1**A illustrates a cross-sectional side view of one embodiment of a fluid delivery and airway management device.

[0009] FIG. **1**B illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device.

[0010] FIG. **2**A illustrates a cross-sectional side view of one embodiment of the device of FIG. **1**A or FIG. **1**B.

[0011] FIG. **2**B illustrates a cross-sectional side view of one embodiment of the device of FIG. **1**A or FIG. **1**B.

[0012] FIG. **3**A illustrates a cross-sectional side view of one embodiment of the device of FIG. **1**A or FIG. **1**B.

[0013] FIG. **3**B illustrates a cross-sectional side view of one embodiment of the device of FIG. **1**A or FIG. **1**B.

[0014] FIG. **4**A illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device.

[0015] FIG. **4**B illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device.

[0016] FIG. **5**A illustrates a cross-sectional side view of one embodiment of the device of FIG. **4**A or FIG. **4**B.

[0017] FIG. **5**B illustrates a cross-sectional side view of one embodiment of the device of FIG. **4**A or FIG. **4**B.

[0018] FIG. **6**A illustrates a cross-sectional side view of one embodiment of the device of FIG. **4**A or FIG. **4**B.

[0019] FIG. **6**B illustrates a cross-sectional side view of one embodiment of the device of FIG. **4**A or FIG. **4**B.

[0020] FIG. **7**A illustrates a cross-sectional side view of one embodiment of he device of FIG. **4**A or FIG. **4**B.

[0021] FIG. **7**B illustrates a cross-sectional side view of one embodiment of the device of FIG. **4**A or FIG. **4**B.

[0022] FIG. **8** is a block diagram illustrating one embodiment of a process for surfactant delivery.

DETAILED DESCRIPTION

[0023] In this section we shall explain several preferred embodiments of this invention with reference to the appended drawings. Whenever the shapes, relative positions and other aspects of the parts described in the embodiments are not clearly defined, the scope of the invention is not limited only to the parts shown, which are meant merely for the purpose of illustration. Also, while numerous details are set forth, it is understood that some embodiments of the invention may be practiced without these details. In other instances, well-known structures and techniques have not been shown in detail so as not to obscure the understanding of this description.

[0024] FIG. **1**A illustrates a cross-sectional side view of one embodiment of a fluid delivery and airway management device positioned within an airway of a user. In one embodiment, device **100** may be positioned within an airway of a patient **102**, which could be a mammal. Representatively, in one embodiment, device **100** is dimensioned for fluid delivery and/or management of an airway of a human patient. It is to be understood that the fluid suitable for delivery by device **100** may be any substance suitable for delivery within an air pathway of patient **102**. The fluid may be any substance capable of flowing and changing shape in response to an applied pressure, for example, a substance in the form of a liquid, gas, aerosol or the like, that is suitable for delivery to an air pathway. For example, in the case of an infant suffering from RDS, the fluid may be a surfactant in a liquid or aerosol form, Alternatively, where device **100** is being used for airway management, the substance delivered may be air.

[0025] In one embodiment, device **100** may be dimensioned for use within a patient which may be a very low birth weight or premature infant, for example, weighing less than 1500 grams, more specifically from about 400 grams to about 1500 grams. In still further embodiments, device **100** is dimensioned for use within a newborn **30** days old or less. In other embodiments, device **100** may be dimensioned for use in an animal of any size and shape (e.g. a dog, a cat, a pig, a horse, a cow, etc.).

[0026] In some embodiments, device **100** may be several sizes depending upon the size of the patient. Representatively, in the case of a premature or very low birth weight infant, device **100** may have a first size for use in an infant less than about 700 grams, a second size for use in an infant from about 800 grains to about 1000 grams and a third size for use in an infant from about 1000 grams to about 1500 grams. In another embodiment, device **100** may have 2 sizes for premature infants—a first size for use in an infant less than about 1000 grams, and a second size for use in an infant over 1000 grams. In the illustrated embodiment, patient **102** is a human.

[0027] As previously discussed, often times when the patient is a premature or an otherwise very low birth weight infant, their lungs are not fully developed and the infant is unable to produce a sufficient amount of surfactant necessary for proper lung function. Thus, it has been found that an air pathway to the lungs can be used to deliver additional surfactant to the infant's lungs. One representative air pathway is illustrated in FIG. **1**A. Representatively, air passage to the lungs occurs when the individual breathes air in through nose **124** or mouth **128**. In the case of the mouth, air passes from mouth **128**, through oral cavity **116** and into the oropharynx **118**, which is the oral part of the pharynx extending from the uvula to the hyoid bone. Air from nose **124** passes through nasal cavity **130** and also into oropharynx **118**. From oropharynx **118**, the pathway splits into the trachea **122**, which extends to the lungs, and the esophagus **120**, which extends to the stomach. Thus, in order to introduce a fluid (e.g. a surfactant or air) to the lungs, device **100** is dimensioned to create a substantially sealed air pathway from mouth **128** to trachea **122**. Representatively, device **100** is dimensioned to deliver fluid **123** (e.g. a surfactant or air) to oropharynx **118** while blocking the esophagus **120** and fluid exits from nose **124** and mouth **128** such that the only way for the fluid **123** to go is from oropharynx **118** to the trachea **122** as indicated by the arrows.

[0028] To create such a sealed pathway, in one embodiment, device **100** includes tubular member **104**, which is dimensioned to extend through mouth **128** to esophagus **108**. In one embodiment, an end portion of tubular member **104** extending from mouth **128** includes one or more openings to allow for the introduction of fluid (e.g. a surfactant or air) and the other end is sealed to prevent air from exiting out the end and into esophagus **120**. Apertures **120** are formed within a portion of tubular member **104** near the sealed end and within oropharynx **118** such that fluid introduced into the open end exits through apertures **120** toward trachea **122**. Device **100** may further include an inflatable oral cavity balloon **106**, which can be inflated within the oral cavity **116** to help position tubular member **104** within the air pathway of patient **102** and prevent fluid from exiting mouth **128** during a ventilation procedure. In addition, device **100** includes an inflatable esophageal balloon **108** positioned near the sealed end of tubular member **104**, which can be inflated within or at an entrance to esophagus **120** to prevent the fluid from entering esophagus **120**. In addition to preventing fluid entry inflatable esophageal balloon **108** may be dimensioned to prevent reflux of gastric content from esophagus **120** without putting excessive pressure on the esophageal wall.

[0029] Device **100** may further include protrusion **110** which extends from a middle portion of tubular member **104** in a direction of tongue **130**. Protrusion may be dimensioned to serve as a tongue holder which holds tongue **130** in place during inflation of oral cavity balloon **106** and prevents tongue **130** from posterior displacement thus blocking the air pathway to trachea **122**. Air management device **100** may also include stabilizer **114**. Stabilizer **114** may be positioned along a portion of tubular member **104** positioned to anchor the gum thus stabilizes the device **100** in the mouth.

[0030] In some embodiments, a nasal continuous positive air pressure (CPAP) device **127** may be used, which provides positive pressure to prevent fluid **123** escape from the nasal passage and drive fluid **123** into the lungs. Representatively, CPAP device **127** may include a nasal tube **125** positioned within nose **124** of patient **102**. Nasal tube **125** may be connected to an air pressure machine **129** that outputs a positive air pressure through nasal tube **125**. The air exits nasal tube **125** into the nasal passage **130** and travels through the previously discussed sealed air passage to the lungs as illustrated by the arrows. As the air travels through the air

pathway toward the lungs, it intersects with any fluid **123** (e.g. a surfactant) within oropharynx **118** and drives fluid **123** into the lungs.

[0031] FIG. **1**B illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device positioned within an airway of a user. Device **100** is substantially similar to the device described in reference to FIG. **1**A except in this embodiment, a nose block **126** may further be provided. Nose block **126** may be any type of nose blocking device such as a nose clip or other mechanism capable of sealing nose **124** and occluding the nostrils and preventing air exits through nose **124**. It is further contemplated that in some embodiments, a pulse oximeter sensor or other similar sensing device may be integrated with, or placed near, the nose block **124** such that the oxygen saturation or other physiologic parameters of the patient can be monitored during a ventilation procedure. For example, nose block **126** could be used when a nasal CPAP device is not used, where the fluid administered through device **100** has already reached the lungs and CPAP ventilation is not required.

[0032] Each of the aspects of device **100** will now be described in further detail in reference to FIG. **2**A, FIG. **2**B, FIG. **3**A and FIG. **3**B. Referring to FIG. **2**A and FIG. **2**B, FIG. **2**A illustrates a cross-sectional side view of device **100** in a deflated configuration and FIG. **2**B illustrates a cross-sectional side view of device **100** in an inflated configuration. FIG. **3**A illustrates a cross-sectional top view of device **100** in a deflated configuration and FIG. **3**B illustrates a cross-sectional top view of device **100** in an inflated configuration.

[0033] Returning to FIG. **2**A-**2**B, from this view it can be seen that tubular member **104** is a hollow tube having a proximal portion **202**, a middle portion **206** and a distal portion **204**. During use, proximal portion **202** is positioned within the oral cavity while distal portion **204** is positioned into the esophagus of the patient. Middle portion **206** of tubular member **104** may form a curve such that tubular member **104** substantially conforms to the structure of the air pathway of the patient and can be advanced through oral cavity **116** to esophagus **120**. In some embodiments, open end **210** of tubular member **104** may have the dimensions of a universal connector used in endotracheal tubes for connection with a self-inflation bag device or ventilator.

[0034] In addition, proximal portion **202** may include a proximal port **222** through a side of tubular member **104**. Port **222** may have any size and shape suitable for introducing a fluid into tubular member **104**. Representatively, in one embodiment, port **222** may be sized such that a syringe containing a fluid such as a surfactant can be injected from the syringe, through port **222** and into tubular member **104**. Once the surfactant is introduced into tubular member **104** through port **222**, the self-inflation bag device or ventilator connected to open end **210** of tubular member **104** may be used to provide a positive air pressure sufficient to drive the surfactant down tubular member **104** and out apertures **112**.

[0035] Port **222** may, however, be optional and, instead, the surfactant can be delivered into tubular member **104** through open end **210**. Representatively, where port **222** is omitted, a surfactant or other fluid substance can be introduced into open end **210** of tubular member **104** using a syringe, or other similar delivery device. Once introduced into tubular member **104**, the self-inflation bag device or ventilator can be connected to open end **210** to deliver a positive pressure into tubular member **104** and drive the surfactant through tubular member **104** and out apertures **112**.

[0036] In some embodiments, tubular member **104** may be made of any semi-rigid material such as polyethylene or a clear polyvinyl chloride (PVC) suitable for insertion along an air passageway of a patient. In addition, in some embodiments, the diameter of tubular member **104** may taper toward sealed end **208** and the material used in the esophageal portion (i.e. distal portion **204**) may be less rigid than other portions of tubular member **104** (e.g. middle portion **206** and/or proximal portion **202**) to avoid esophageal injury.

[0037] Inflatable oral cavity balloon **106** may be mounted to proximal portion **202** of tubular member **104** so that when tubular member **104** is in place, oral cavity balloon **106** is positioned within oral cavity **116** as illustrated in FIG. **1**A or FIG. **1**B. In one embodiment, inflatable oral cavity balloon **106** may be positioned at a region of tubular member **104** and dimensioned such that it only occludes oral cavity **116** and does not occlude nasal cavity **130**. In other words, oral cavity balloon **106** may be confined to the oral cavity **116** and does not extend to other regions such as the oropharynx **118**, or other regions adjacent middle portion **206**. Rather, oral cavity balloon **106** is positioned between stabilizer **114**, and in some cases contacting stabilizer **114**, and the bend portion of middle portion **206**. Inflatable oral cavity balloon **106** may be substantially symmetric in the inflated configuration as shown. In other embodiments, oral cavity balloon **106** may be substantially asymmetric in the inflated configuration. Representatively, the distal end of oral cavity balloon **106** may have a larger diameter than the proximal end. This type of structure may help to compress and push the tongue forward such that oral cavity balloon **106** can also serve as a tongue holder. Alternatively, the distal end of oral cavity balloon **106** may have a smaller diameter than the proximal end to facilitate blocking of the oral cavity.

[0038] Oral cavity balloon **106** may be a substantially compliant balloon made of materials including, but not limited to, latex, polyurethane, nylon elastomers and other thermoplastic elastomers. In this aspect, oral cavity balloon **106** can be inflated until it fills the oral cavity and provides a seal in order to prevent fluid leak through the mouth. Oral cavity balloon **106** may be inflated and/or deflated by connecting a syringe not shown) to inflation tube **214** which extends along tabular member **104** to oral cavity balloon **106**. A connector at inflation tube **214** has a valve that opens when a syringe is connected, thus allows air to be injected to or withdrawn from the tube **214** and balloon **106**. Injecting air via the syringe will in turn deliver air to oral cavity balloon **106** causing oral cavity balloon **106** to inflate. Oral cavity balloon **106** may be deflated by withdrawing air through inflation tube **214** using the syringe. In some embodiments, inflation tube **214** may extend through the lumen of tubular member **104** and through the wall to oral cavity balloon **106**. Alternatively, inflation tube **214** may extend along the outside of tubular member **104**.

[0039] In some embodiments, esophageal balloon **108** may also be connected to inflation tube **214**. In this aspect, oral cavity balloon **104** and esophageal balloon **108** may be inflated or deflated at the same time or in sequence (by varying the resistance of balloons to allow esophageal balloon to fill up first then the oral cavity balloon). In other embodiments where independent inflation/deflation of esophageal balloon **108** is desired, a separate inflation tube

may be connected to esophageal balloon **108**. As previously discussed, esophageal balloon **108** is used to block the opening to esophagus **120** as illustrated in FIG. **1**A and FIG. **1**B. Esophageal balloon **108** may therefore be mounted to distal portion **204** of tubular member **204**, near sealed end **208**. Esophageal balloon **108** may be less compliant than oral cavity balloon **104** such that it can be inflated to a predetermined maximum size suitable for blocking an opening of the esophagus (e.g. to block acid reflux from the stomach) without putting excessive pressure on the esophageal wall. Representatively, in one embodiment, esophageal balloon **108** may be made of a polyethylene or other low-compliance polymer and have a maximum diameter which is substantially equal to that of the esophageal opening.

[0040] To facilitate positioning of oral cavity balloon **104** and esophageal balloon **108** at the desired region within the patient, tubular member **104** may have a length (and bend as previously discussed) such that when tubular member **104** is positioned within the patient, oral cavity balloon **104** is positioned within oral cavity **116** and esophageal balloon **108** is positioned within the superior portion of esophagus **120**. Representatively, tubular member **104** may have any length and oral cavity balloon **104** and esophageal balloon **108** any dimension/shape suitable for positioning of device **100** within an airway path as described above for patients within any of the previously discussed age and size ranges. The dimensions and shape of tubular member **104**, oral cavity balloon **104** and esophageal balloon **108** may also be suitable for use of the device **100** within a patient that is an animal (e.g. a horse, a cow, a pig, a dog, a cat, etc).

[0041] Protrusion **110** may extend from tubular member **104**, near or within proximal portion **202** so that it is aligned with the tongue when air maintenance device **100** is positioned within the oral cavity. In some embodiments, protrusion **110** may have a substantially triangular profile with the distal portion being the base of the triangle and extending further from tubular member **104** farther than the proximal portion. In this aspect, the wider portion of protrusion **110** pushes the back portion of the tongue away from apertures **112** formed within proximal portion **206** so that it does not block apertures **112**, or other air pathways.

[0042] Apertures **112** are formed within the middle portion **206** of tubular member **104** so that they are aligned within the oropharynx **118** (see FIG. **1**A and FIG. **1**B) of the patient when device **100** is in place. Although a plurality of apertures **112** are shown, it is contemplated that any number and diameter of apertures **112** suitable for outputting fluid to the trachea of the patient may be formed through tubular member **104**. Representatively, in some embodiments, there may be only one of apertures **112** (e.g. one large aperture) while in another embodiment there is more than one of apertures **112** (e.g. a plurality of smaller apertures). In this aspect, when fluid (e.g. a surfactant or air) is pumped through tubular member **104**, the fluid will flow through apertures **112** to the oropharynx. Since the exits to the mouth, nose and esophagus are sealed via oral cavity balloon **106**, CPAP device **127** or nose block **126**, and esophageal balloon **108**, respectively, the pumped air will be forced by positive pressure to the trachea during inspiration. In addition, any expired air from the trachea can exit the trachea through tubular member **104** during expiration.

[0043] In some embodiments, nose block **126** may be attached to device **100** while in others nose block **126** may be separate from device **100** or omitted. Representatively, nose block **126** may be attached to device **100** by a chord **212** attached to the proximal portion **202** of tubular member **104** so that nose block **126** is near the patient's nose when device **100** is inserted within the patient's mouth. Once device **100** is in the desired position, nose block **126** can be positioned around the patient's nose to block air from exiting the nose. As previously discussed, nose block **126** may be any type of nose clip or other mechanism capable of restricting air passage through the patient's nose (e.g. a nose plug).

[0044] FIG. **3**A and FIG. **3**B illustrate top views of device **100** in the deflated and inflated configurations, respectively. From this view, it can be seen that protrusion **110** may have a width dimension greater than that of tubular member **104** such that it extends beyond the sides of tubular member **104**. In some embodiments, protrusion **110** may have a width dimension substantially similar to that of the patient's tongue width such that it can hold a substantial portion of the tongue in the desired position without the sides of the tongue curling up. It can further be seen from this view that in some embodiments, apertures **112** can extend around a substantial portion of the circumference of tubular member **104**. For example, apertures **112** may be formed within both the sides of tabular member **104** near or facing the trachea and the top of tubular member **104**.

[0045] One representative way of using device **100** will now be described. For example, in one embodiment, device **100** having the appropriate dimensions for the patient is selected by the care provider. With both the oral cavity balloon **106** and esophageal balloon **108** deflated, tubular member **104** is placed within the patient's mouth and pointed posterior to prevent the tube from entering into the trachea. This part can be performed by properly placing the patient's head and opening the mouth manually without the use of a laryngoscope. Tubular member **104** is then advanced until protrusion **110** is aligned with the base of the tongue. A syringe (not shown) is connected to the inflation tube **214**. Using the syringe, air is then pumped through inflation tube **214** and into oral cavity balloon **106** and esophageal balloon **108** until the oral cavity balloon **106** fills up and occludes the oral cavity so that air cannot exit. CPAP device **127** or nose block **126** may further be placed on the nose to block the nasal airway.

[0046] In embodiments where device **100** is used to deliver a fluid such as a surfactant to the lungs, the surfactant can be delivered into tubular member **104** through open end **210** or port **222**, where provided, using a syringe or other similar delivery device.

[0047] Next, a self-inflation bag device or other device capable of providing positive pressure ventilation, is attached to the open end **210** universal connector of tabular member **104**. The user then compresses the bag to pump air through tubular member **104** and drive the surfactant into the trachea via apertures **112**. The steps of introducing the surfactant to tubular member **104** and introducing positive pressure may be repeated as necessary. For example, in some embodiments, it is desirable to deliver the surfactant to the lungs in separate doses. Thus, a first amount of the surfactant may be introduced into tubular member **104** and pumped into the lungs using a positive pressure. When open end **210** is connected to a self-inflation bag device and port **222** is connected to a syringe filled with surfactant fluid, the operator will inject the surfactant into port **222** first, fol-

lowed immediately by pumping air through open end **210** by the bag device to optimize the delivery of surfactant to the lungs. Once the first amount reaches the lungs, a second amount of surfactant may be introduced into tubular member **104** and positive pressure applied again to drive the second amount of surfactant into the lungs.

[0048] In embodiments where device **100** is used primarily for ventilation, any one or more of the previously described steps can be followed with or without surfactant introduction. Successful placement of device **100** and adequate ventilation can be assessed by observing chest rise of the patient and auscultation of air movement using a stethoscope.

[0049] FIG. **4**A illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device positioned within an airway of a user. In one embodiment, device **400** may be positioned within an airway of a patient **402**, which could be a mammal of any age and size as previously discussed in reference to FIG. **1**A. Device **400** may be substantially similar to device **100** described in reference to FIG. **1**A except that in this embodiment, device **400** includes an oral airway tube **404** and an esophageal tube **403** positioned concentrically inward of the oral airway tube **404**. Oral airway tube **404** is dimensioned to pass from the mouth **428**, through oral cavity **416** and to the base of the tongue **430**. An inflatable oral cavity balloon **406** is attached to oral airway tube **404** so that in the inflated configuration, oral cavity balloon **406** can be used to block air exit from mouth **428**. Esophageal tube **403** is dimensioned to extend through oral airway tube **404**, from the mouth **428** to the esophagus **420**. An inflatable esophageal balloon **408** is attached to the end of esophageal tube **403** near esophagus **420** and aperture **412** is formed within the portion of esophageal tube **403** positioned within the oropharynx **418**. Similar to device **100**, the patient's oral airway and nasal airway may be blocked using oral cavity balloon **416** and CPAP device **427**, respectively, and the pathway to esophagus **420** blocked using esophageal tube **403** such that the only way for air pumped through esophageal tube **403** to go is out aperture **412** to trachea **422**.

[0050] Device **400** may also include stabilizer **414**. Stabilizer **4114** may be positioned along a portion of oral airway tube **404** positioned near the gum so that if patient **402** bites down during the ventilation procedure, the force from the bite does not obstruct operation of device **400**. Stabilizer **414** may further serve as a guide to help properly position device **400** within the patient **402**.

[0051] In some embodiments, a nasal continuous positive air pressure (CPAP) device **427** may further be provided to seal the nasal passage and drive fluid **423** into the lungs. Representatively, CPAP device **427** may include a nasal tube **425** positioned within nose **124** of patient **102**. Nasal tube **425** may be connected to an air pressure machine **429** that outputs a positive air pressure through nasal tube **425**. The air exits nasal tube **425** into the nasal passage **130** and travels through the previously discussed sealed air passage to the lungs as illustrated by the arrows. As the air travels through the air pathway toward the lungs, it intersects with any fluid **423** (e.g. a surfactant) within oropharynx **118** and drives fluid **423** into the lungs.

[0052] In some embodiments, although not illustrated, an optional tongue holder may further be provided to hold tongue **430** in place during inflation of oral cavity balloon **406**.

[0053] FIG. **4**B illustrates a cross-sectional side view of another embodiment of a fluid delivery and airway management device positioned within an airway of a user. Device **100** is substantially similar to the device described in reference to FIG. **4**A except in this embodiment, a nose block **426** may further be provided. Nose block **426** may be any type of nose blocking device such as a nose clip or Other mechanism capable of sealing nose **424** and occluding the nostrils and preventing air exits through nose **424**. It is further contemplated that in some embodiments, a pulse oximeter sensor or other similar sensing device may be integrated with, or placed near, the nose block **424** such that the oxygen saturation or other physiologic parameters of the patient can he monitored during a ventilation procedure. For example, nose block **426** could be used when a nasal CPAP device is not necessary, for example, where the fluid administered through device **400** has already reached the lungs and CPAP ventilation is not required.

[0054] Each of the aspects of device **400** will now be described in further detail in reference to FIG. **5**A, FIG. **5**B, FIG. **6**A, FIG. **6**B, FIG. **7**A and FIG. **7**B. FIG. **5**A and FIG. **5**B illustrate cross-sectional side views of one embodiment of the oral airway tube of FIG. **4**A and FIG. **4**B in a deflated configuration and an inflated configuration, respectively. In one embodiment, oral airway tube **404** includes a proximal portion **502** terminating at a proximal end **540**, and a distal portion **504** terminating at a distal end **542**. When device **400** is positioned within the airway of the patient, proximal end **504** may be near mouth **428**, and in some cases extend from mouth **428**, while distal end **542** is positioned near the base of the tongue. Each of the proximal end **540** and the distal end **542** are open and oral airway tribe **404** may have a lumen large enough to allow for insertion of esophageal tube **403** therethrough. Proximal end **540** can also be dimensioned to accommodate a universal adaptor that can be connected to a self-inflation bag device or other ventilating device. In some embodiments, oral airway tube **504** may be a semi-rigid tube made of, for example, polyethylene.

[0055] Oral cavity balloon **406** may be attached to the proximal portion **402** of oral airway tube **404** and positioned within the oral cavity of the patient during use. Oral cavity balloon **406** may be a substantially compliant inflatable/deflatable balloon having an outer diameter sufficient to fill the oral cavity and provide a substantially complete seal in order to prevent air leak via the mouth. In some embodiments, oral cavity balloon **406** may be an asymmetrical balloon such that when it is inflated, the proximal end diameter is greater than that of the distal end, or the distal end diameter is greater than that of the proximal end. Oral cavity balloon **406** may be made of any compliant material such as latex, polyurethane, nylon elastomers and other thermoplastic elastomers. Stabilizer **414** may be attached to the proximal portion **502** of oral airway tube **404** such that it is aligned with the gum of the patient when oral airway tribe **404** is positioned within the patient's oral cavity.

[0056] Oral cavity balloon **406** may be inflated and/or deflated by connecting a syringe (not shown) to inflation tube **514** which extends along oral airway tube **404** to oral cavity balloon **406**. Injecting air into the syringe will in turn deliver air to oral cavity balloon **406** causing oral cavity balloon **406** to inflate. Oral cavity balloon **406** may be deflated by withdrawing air through inflation tube **514** using the syringe. In some embodiments, inflation tube **514** may extend through the lumen of oral airway tube **404** and

through the wall to oral cavity balloon **406**. Alternatively, inflation tube **514** may extend along the outside of oral airway tube **404**.

[0057] FIG. **6**A and FIG. **6**B illustrate cross-sectional side views of the esophageal tube of FIG. **4**A and FIG. **4**B in a deflated and an inflated configuration, respectively. Esophageal tube **403** includes a proximal portion **602** terminating at a proximal end **640**, and a distal portion **604** terminating at a distal end **642**. Esophageal tube **403** may further include a middle portion **606**, between proximal portion **602** and distal portion **604**, and having a bend so that esophageal tube **403** can conform to a shape of the air pathway of the patient. Esophageal tribe **403** may have a length such that when device **400** is positioned within the airway of the patient, proximal end **604** may be near mouth **428**, and in some cases extend from mouth **428**, while distal end **642** is positioned near, or within, the esophagus **420**. Proximal end **640** may be a substantially open end and the distal end **642** may be a sealed end such that air pumped into esophageal tube **604** can only exit through aperture **412**. Proximal portion **602** may further include a proximal delivery port **622** through the side wall of tube **403** fur introducing a fluid (e.g. a surfactant) into tube **403**.

[0058] Esophageal tube **403** may have an outer diameter smaller than the inner diameter of the inner diameter of the oral airway tube **504** such that it can be inserted within and through oral airway tube **404**. In some embodiments, when esophageal tube **403** is inserted through oral airway tube **504**, proximal end **640** may be dimensioned to extend from the proximal end **540** of oral airway tube **504** and accommodate a universal adaptor that can be connected to a self-inflation bag device or other ventilating device. In some embodiments, esophageal tube **403** may be made of a clear PVC, or other similar material.

[0059] In some embodiments, esophageal balloon **408** is connected to the distal portion **604** of esophageal tube **403**. An inflation tube **614**, separate from inflation tube **514**, may extend from the proximal end **602** to the distal end **604** and connect to esophageal balloon **408** to allow for inflation and deflation of esophageal balloon **408**. Inflation tube **614** may run along the inner lumen of esophageal tube **403** or outside of esophageal tube **403**. As previously discussed, esophageal balloon **408** is used to block the opening to esophagus **420** as illustrated in FIG. **4**A. In some embodiments, esophageal balloon **408** may be less compliant than oral cavity balloon **404** such that it can be inflated to a predetermined maximum size suitable for blocking an opening of esophagus **420** (e.g. to block acid reflux from the stomach) without putting excessive pressure on the esophageal wall. Representatively, in one embodiment, esophageal balloon **408** may be made of a polyethylene or other low-compliance polymer and have a maximum diameter which is substantially equal to that of the esophageal opening.

[0060] Esophageal tube **403** may further include aperture **412** formed within distal portion **604**. Aperture **412** may be a single opening or a plurality of openings formed through a portion of the wall of esophageal tube **403**.

[0061] A stopper **620** may further be attached to the distal portion **602** of esophageal tube **403**. Stopper **620** may be dimensioned to prevent proximal end **640** of esophageal tube **403** from being inserted through oral airway tube **404**. In one embodiment, stopper **620** may be a ring shaped member which increases a diameter of oral airway tube **404**. In this aspect, during an assembly operation, distal end **642** of esophageal tube **403** can be inserted through the proximal end **540** of oral airway tube **404** and pulled out the distal end **542** of oral airway tube **404** until stopper **620** reaches stabilizer **414** as illustrated in FIG. **7**A and FIG. **7**B.

[0062] FIG. **7**A and FIG. **7**B illustrate cross-sectional side views of the assembled device **400**. From this view, it can be seen that when esophageal tube **403** is inserted through oral airway tube **404**, oral airway tube **404** may overlap esophageal tube **403** along its proximal portion **602** and middle portion **606** such that the proximal end **640** and distal portion **604** of esophageal tube **403** are exposed. In this aspect, aperture **412** is positioned between the distal end **542** of airway tube **404** and the distal end **642** of esophageal tube **403**, and exposed to the oropharynx (see FIG. **4**). Since all the airway paths other than the trachea **422** are blocked by oral cavity balloon **404**, esophageal balloon **408** and nose block **426**, air exiting aperture **412** to the oropharynx **418** passes to trachea **422** and to the lungs. It is noted that in some embodiments, optional nose block **426** is attached to oral airway tube **404** or esophageal tube **403** via chord **712** as illustrated, while in other embodiments, nose block **426** is separated from device **400**.

[0063] One representative way of using device **400** will now be described. For example, in one embodiment, the device **400** having the appropriate dimensions for the patient is selected by the care provider (e.g. EMT). Oral airway tube **404** and esophageal tube **403** may be inserted into the patients airway separated or as an assembled unit. For example, in one embodiment, oral airway tube **404** is first inserted into the patient's oral cavity followed by insertion of esophageal tube **403** through oral airway tube **404**, Alternatively, esophageal tube **403** is inserted through oral airway tube **404** prior to positioning within the patient, and then the two together are inserted within the patient's mouth as a preassembled unit. In either case, both the oral cavity balloon **406** and esophageal balloon **408** are deflated prior to insertion of the tubing and then inflated once oral cavity balloon **406** is within the oral cavity and esophageal balloon **408** is within, or near the esophagus. Nose block **426** may then be placed on the nose to block the nasal airway.

[0064] A syringe (not shown) is connected to the inflation tubes **514** and **614**. Using the syringe, air is then pumped through inflation tubes **514** and **614** and into oral cavity balloon **406** and esophageal balloon **408**, respectively, until the oral cavity balloon **406** completely occludes the oral cavity so that air cannot exit. Connectors at inflation tubes **514** and **614** have a valve that opens when a syringe is connected, thus allows air to be injected to or withdrawn from the tubes **514** and **614** and balloons **406** and **408**.

[0065] In embodiments where device **400** is used to deliver a fluid such as a surfactant to the lungs, the surfactant is introduced into tube **403** through port **622**. A self-inflation bag device, or other device capable of providing positive pressure ventilation, is attached to the proximal end **640** of esophageal tube **403**. The care provider then introduces a positive air pressure into tube **403** to drive the fluid through tube **403** and/or ventilate the patient by compressing the bag.

[0066] It is to be understood that any of the above described devices can be packaged as a kit with each of the parts pre-assembled or unassembled and the balloons deflated. The kit may come in a variety of different sizes to accommodate a variety of different patients. For example, in one embodiment, the device may be manufactured in three different sizes to accommodate a premature or otherwise

very low birth weight infant within the weight ranges of (1) up to 700 grams, (2) about 700 g to about 1000 grams and (3) about 1000 grams to about 1500 grams. In still further embodiments, device 100 may have 2 sizes for premature infants—a first size for use in an infant less than about 1000 grams, and a second size for use in an infant over 1000 grams.

[0067] It is further to be understood that any of the above described devices can be used to deliver a sufficient amount of surfactant continuously or serially in the absence of endotracheal intubation. Thus, the devices disclosed herein provide an effective and safe surfactant delivery system which requires much lower skills of the operator and avoids many complications associated with endotracheal intubation. Representatively, in one embodiment where the device is used for surfactant delivery, the care provider performs the following steps:

[0068] First, the appropriate sized device is selected based upon the size of the infant. Next, the infant is positioned supine with mouth open, the oropharynx is cleared, and nasal CPAP device is placed on the infant as needed. The device is then gently inserted into the esophagus. A syringe for inflating the balloons is connected to the inflation port followed by inflation of the esophageal cuff and oral cavity balloon until visually the balloon fills up the oral cavity with a seal around the cheek. The surfactant is then delivered into the tube (e.g. using a syringe). A self-inflation bag device is then connected to the tube and compressed to deliver a flow of air into the tube and drive the surfactant out the apertures toward the lungs. The device may be safely left in place as the infant continues on nasal CPAP. Thus, if the infant's respiratory status worsens despite the use of nasal CPAP, the care provider can use the device to connect to the bag-valve device or ventilator to deliver positive pressure ventilation.

[0069] In some embodiments, the surfactant is delivered in multiple doses or repeat doses and at a frequency dependent upon the clinical status of the patient. For example, in some embodiments, the surfactant is delivered in 6 to 24 hour intervals. It is noted that since the devices disclosed herein provide a substantially sealed delivery pathway to the lungs, as opposed to other methodologies such as nasal administration, the number of doses, frequency, and in some cases, dosage amount, may be reduced below that typically administered because substantially all of the surfactant reaches the lungs.

[0070] The surfactant may be any approved surfactant which mimics pulmonary surfactant. Representatively, the surfactant may be a natural exogenous surfactant or a synthetically manufactured surfactant. Representatively, the surfactant may be in fluid or in aerosol forms. Representative surfactants may include, but are not limited to, poractant alfa, calfactant, beractant and lucinactant. Representative doses may include, but are not limited to, from about 100-200 mg/kg/dose (1.25-2.5 mL/kg), 105 mg/kg/dose (3 mL/kg), 100 mg/kg/dose (4 mL/kg) and 5.8 mL/kg.

[0071] FIG. **8** is a block diagram illustrating one embodiment of a process for surfactant delivery. In one embodiment, process **800** may include positioning a tubular member within an airway of a mammal (block **802**). The tubular member may be, for example, any of the previously discussed tubular members such as tubular member **104** discussed in reference to device **100**. Process **100** may further include inflating an esophageal balloon attached to a distal portion of the tubular member, within an esophagus of the mammal, so as to occlude the esophagus (block **804**). The esophageal balloon may be, for example, esophageal balloon **108** described in reference to device **100**. In addition, an oral cavity balloon attached to a proximal portion of the tubular member, within an oral cavity of the mammal, may be inflated so as to occlude the oral cavity (block **806**). The oral cavity balloon may be, for example, oral cavity balloon **106** described in reference to device **100**. A surfactant may then be introduced into one end of the tubular member (block **808**). Next, a positive air pressure may be applied through the one end of the tubular member to drive the surfactant through the tubular member and out an aperture within the tubular member (block **810**). In addition, an air flow may be delivered into a trachea of the mammal to drive the surfactant toward a lung (block **812**).

[0072] It is to be understood that in the case of fluid delivery, specifically surfactant delivery, the devices disclosed herein provide several advantages including: 1) more secure pathway for surfactant delivery; 2) a temporary rescue airway for premature and very low birth weight infants; 3) fewer injuries as compared to endotracheal intubation techniques which can cause vocal cord injury, tracheal perforation and airway trauma; 4) faster surfactant delivery; 5) more efficient surfactant delivery (e.g. a lower dosage can be used since the delivery pathway is directly to the lungs); and 6) lower skill than endotracheal intubation.

[0073] In the preceding detailed description, specific embodiments are described. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the claims. The specification and drawings are, accordingly, to be regarded in an illustrative rather than restrictive sense.

We claim:

1. A fluid delivery apparatus comprising:

a tubular member dimensioned for introducing fluid into a trachea of a mammal, the tubular member having a proximal portion, a distal portion, and a middle portion between the proximal portion and the distal portion, wherein the tubular member is dimensioned for positioning of the proximal portion in an oral cavity of a mammal, the middle portion in an oropharynx of the mammal and the distal portion in an esophagus of the mammal;

an inflatable oral cavity balloon positioned at the proximal portion and dimensioned to occlude inside the oral cavity by inflating within the oral cavity and not contact the oropharynx;

an inflatable esophageal balloon positioned at the distal portion and dimensioned to occlude the esophagus; and

apertures formed within the middle portion such that fluid introduced into the tubular member is output through the apertures to a trachea.

2. The apparatus of claim **1** wherein the fluid is a surfactant.

3. The apparatus of claim **1** further comprising a fluid inlet port formed through a side of the proximal portion.

4. The apparatus of claim **1** further comprising:

a protrusion extending from the middle portion and dimensioned to hold a tongue at a desired position.

5. The apparatus of claim **1** further comprising:

a nose block device.

6. The apparatus of claim **1** further comprising:

an inflation tube in communication with the inflatable oral cavity balloon and the inflatable esophageal balloon so

as to allow for inflation of the inflatable oral cavity balloon and the inflatable esophageal balloon.

7. The apparatus of claim **1** wherein the inflatable oral cavity balloon is asymmetric and dimensioned to both occlude the oral cavity and hold a tongue at a desired position.

8. The apparatus of claim **1** wherein the inflatable esophageal balloon is dimensioned to occlude an entire lumen of the esophagus and prevent reflux of gastric content out of the lumen.

9. The apparatus of claim **1** wherein the fluid is air.

10. The apparatus of claim **2** wherein the surfactant is a liquid.

11. The apparatus of claim **1** wherein the fluid is a gas.

12. The apparatus of claim **2** wherein the surfactant is an aerosol.

13. The apparatus of claim **2** wherein the surfactant is a poractant alfa, a calfactant, a beractant, or lucinactant.

14. The apparatus of claim **2** wherein the surfactant is present at about 100-200 mg/kg/dose.

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