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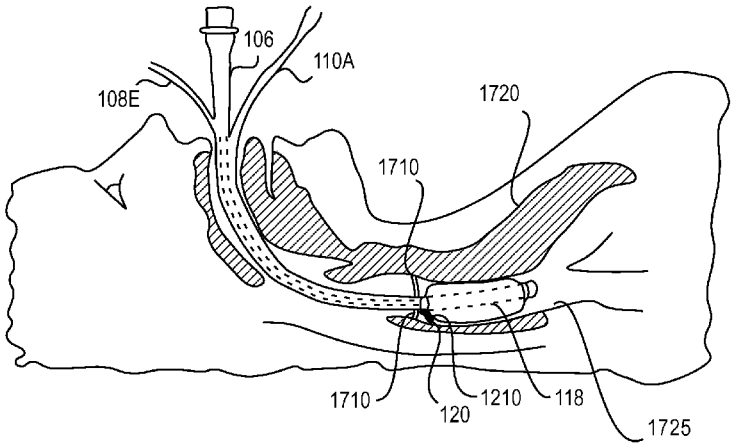


FIG. 17

(57) Abstract: Tracheal tube systems may include first and second tubes and an inflatable balloon. The first tube may be flexible and hollow and have first and second open ends. The inflatable balloon may be affixed to and circumferentially surround a portion of the first tube. The inflatable balloon may include an indentation sized and positioned to accommodate a portion of a second tube positioned therein, when the inflatable balloon is inflated. The second tube may be hollow and have a multiplicity of holes along a sidewall not in contact with the balloon. The second tube may be configured to be coupled to a suction device that creates a negative pressure in the second tube. When the tracheal tube system is inserted in a patient's trachea, the negative pressure in the second tube may act to remove, or suction out, fluids and other matter from the trachea.

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TRACHEAL TUBE AND SUCTION DEVICE

RELATED APPLICATIONS

[001] This application is a continuation-in-part of United States Patent Application Serial Number 14/149,403, filed January 7, 2014 entitled "TRACHEAL TUBE," which is a continuation-in-part of United States Patent Application Serial Number 14/051,443, entitled "TRACHEAL TUBE," filed October 10, 2013, both of which are incorporated herein by reference, in their entirety.

TECHNICAL FIELD

[002] This specification generally relates to the field of tracheal tubes and suction devices.

BACKGROUND

[003] The subject matter discussed in the background section should not be assumed to be prior art merely as a result of its mention in the background section. Similarly, a problem and the understanding of the causes of a problem mentioned in the background section or associated with the subject matter of the background section should not be assumed to have been previously recognized in the prior art. The subject matter in the background section may merely represents different approaches, which in and of themselves may also be inventions.

[004] Tracheal tubes with inflatable balloons with suction means are broadly known in the prior art. However, the suctioning means of such prior arts are inefficient with suctioning secretions above and around the balloon, therefore allowing secretions and/or pathogens to travel through the balloon and tracheal walls and into the airflow of the tracheal tube. In certain situations, the secretions / pathogens get aerosolized by the high velocity of the ventilated air traveling through the tracheal tube and into the patient's lungs. Aerosolized pathogens traveling at high velocity may send the pathogens deep into the lungs, which may cause Ventilator Associated Pneumonia (VAP).

[005] The present invention is illustrated by way of example, and not limitation, in the figures of the accompanying drawings, in which:

[006] FIG. 1 shows a diagram of an embodiment of a tracheal tube.

[007] FIG. 2A shows a diagram similar to that of FIG. 1 but illustrating another embodiment of a tracheal tube.

[008] FIG. 2B shows a diagram yet another embodiment of a tracheal tube.

[009] FIG. 3 shows a cross-sectional view of an embodiment of the catheter of FIG. 1 taken longitudinally through the catheter along the 3—3 cut line of FIG. 1.

0FIG. 4 shows a cross-sectional view of an embodiment of a catheter and a balloon of FIG. 1 taken longitudinally through the catheter and the balloon along the 4—4 cut line of FIG. 1.

[0010] FIG. 5 shows a drawing of an embodiment of a balloon assembly.

[0011] FIG. 6A shows a flowchart of an embodiment of a method for inserting the endotracheal tube.

[0012] FIG. 6B shows a flowchart of an embodiment of a method for removing the endotracheal tube.

[0013] FIG. 7A shows a flowchart of an embodiment of a method for suctioning secretion from the border of the cuff and trachea region.

[0014] FIG. 7B shows a flowchart of an embodiment of a method for rinsing fluid dispensing device is applying a rinsing fluid.

[0015] FIG. 7C shows a flowchart of an embodiment of a method for artificially ventilating a patient.

[0016] FIG. 8 shows a flowchart of an embodiment of a method manufacturing a tracheal tube.

[0017] FIG. 9 shows a flowchart of an embodiment of a method for manufacturing a tracheal tube.

[0018] FIG. 10 shows a flowchart of an embodiment of a method for creating a balloon.

[0019] FIG. 11 shows a flowchart of an embodiment of a method for attaching a balloon to the endotracheal tube.

[0020] FIGs. 12A and 12B show an embodiment of a tracheal tube.

[0021] FIG. 13 shows a drawing of an embodiment of a balloon assembly.

[0022] FIGs. 14A-14E show embodiments of shaped suction tubes.

[0023] FIGs. 15A and 15B show an embodiment of a tracheal tube.

[0024] FIGs. 16A and 16B show embodiments of exemplary ablative and cystoscopy surgery tools.

[0025] FIG. 17 shows a cross-section view of a patient with tracheal tube system positioned within his trachea.

SUMMARY

[0026] Tracheal tube systems may include first and second tubes and an inflatable balloon. The first tube may be flexible and hollow and have first and second open ends. The inflatable balloon may be affixed to and circumferentially surround a portion of the first tube. The first end of the first tube is configured to be coupled to an artificial ventilation device and the first tube and may be configured so as to allow air or other gases provided by the artificial ventilation device to flow through the first tube into the lungs of an intubated (with the tracheal tube system) patient.

[0027] The inflatable balloon may be positioned between the first and second ends of the first tube and include an indentation sized and positioned to accommodate a portion of a second tube positioned therein, when the inflatable balloon is inflated. In

some embodiments, the indentation may extend around a circumference, or a portion of a circumference, of the inflatable balloon.

[0028] In some embodiments, a portion of the indentation is positioned on the inflatable balloon coincident, or nearly coincident, with a junction between the inflatable balloon and the first tube. The junction may be positioned between the first end of the tube and the balloon.

[0029] The second tube may be hollow and have a multiplicity of holes along a sidewall not in contact with the balloon. In some instances, the second tube may be curved or pre-configured into a particular shape (e.g., triangle, circle, etc.). The second tube may be flexible, rigid, or some combination of both. In some circumstances, the second tube may be an assembly of two or more components. The second tube may be affixed to the balloon within the indentation via, for example, a chemical- or heat-generated bond, a sleeve, a strap, and/or a clamp.

[0030] The second tube may be configured to be coupled to a suction device that creates a negative pressure in the second tube. On some occasions, the first tube may have a lumen coupled to the suction device and negative pressure in the lumen may cause negative pressure in the second tube. When the tracheal tube system is inserted in a patient's trachea, the negative pressure in the second tube may act to remove, or suction out, fluids and other matter from the trachea. In some cases, when the tracheal tube system is placed in a trachea, the negative pressure created by the suction device may act to hold the second tube against an inner surface or wall of the trachea thereby preventing movement of the secretions beyond the balloon and into the lower trachea or lungs.

[0031] In some embodiments, the indentation and the second tube may be positioned relative to the inflatable balloon such that when the tracheal tube system is inserted into a trachea, the balloon is inflated, and negative pressure is applied to the second tube by the suction device, the second tube is positioned against a portion of the tracheal wall, such as the posterior portion of the tracheal wall.

DETAILED DESCRIPTION

[0032] Although various embodiments of the invention may have been motivated by various deficiencies with the prior art, which may be discussed or alluded to in one or more places in the specification, the embodiments of the invention do not necessarily address any of these deficiencies. In other words, different embodiments of the invention may address different deficiencies that may be discussed in the specification. Some embodiments may only partially address some deficiencies or just one deficiency that may be discussed in the specification, and some embodiments may not address any of these deficiencies.

[0033] In general, at the beginning of the discussion of each of FIGs. 1-5 is a brief description of each element, which may have no more than the name of each of the elements in the one of FIGs. 1-5 that is being discussed. After the brief description of each element, each element is further discussed in numerical order. In general, each of FIGs. 1-5 is discussed in numerical order and the elements within FIGs. 1-5 are also usually discussed in numerical order to facilitate easily locating the discussion of a particular element. Nonetheless, there is no one location where all of the information of any element of FIGs. 1-5 is necessarily located. Unique information about any particular element or any other aspect of any of FIGs. 1-5 may be found in, or implied by, any part of the specification.

[0034] FIG. 1 shows a diagram of an embodiment of a tracheal tube system 100. The tracheal tube system 100 may include at least one connector 102, a catheter 106 having opposed open proximal end 104 and open distal end 122, a suction device 108A, an air dispenser device 108B, a fluid dispenser device 108C, a fluid reservoir 108D, at least one suction tube 108E, at least one inflation tube 110A, a pilot balloon 110B, inflation fluid supplying device 110C, at least one suction tube lumen 112, at least one inflation tube lumen 114, at least one suction line exit 116, at least one balloon 118, at least one suction line 120, at least one enlarged opening 124, and at least one enlarged air passage way 126. In other embodiments the tracheal tube system 100 may not have all of the elements or features listed and/or may have other elements or features instead of or in addition to those listed. For example, the balloon 118 may be closed at both ends (i.e., the portion of the balloon 118 closest to the open distal end 122 may be closed so as to seal off the enlarged air passageway 126.

[0035] The tracheal tube system 100 is a tracheal tube with a 360-degree suction line and an enlarged airflow passage. In an embodiment, suctioning is set at 15 mm Hg negative pressure. The tracheal tube system 100 may be adapted to be used for various tubes such as endotracheal, endobronchial, and tracheostomy tubes. The endotracheal tube 100 is a catheter that is inserted into the trachea through the mouth or nose in order to maintain an open air passage or to deliver oxygen, medications, or to permit the suctioning of mucus or to prevent aspiration of oral secretions. Endotracheal tube 100 may be a flexible, hollow cylindrical tube that is open at both ends to allow air to pass through.

[0036] The connector 102 is a connection adapted to connect to a mechanical ventilator. The connector 102 attaches the tracheal tube system 100 to a mechanical ventilator. In an embodiment, the connector 102 may have a length of 4cm, a proximal Outer Diameter (OD) of 1.5 cm, a proximal Inner Diameter (ID) of 1.3 cm, and a proximal length of 1.5 cm. The cross-sectional area of the safety (which is the collar) is 1.5cm x 2.5 cm. In an embodiment, the length of the safety is .5 cm. In an embodiment, the distal opening outer diameter (OD) of connector 102 is .8 cm. In an embodiment, the distal length of connector 102 is 2 cm. In an embodiment the tolerance for all of the listed dimensions in this specification is +/- 10% of the value of the dimension in question. In another embodiment the tolerances in this specification is +/- 5% of the dimension in question. In an embodiment, the connector 102 is made from hard polypropylene. In other embodiments, the mechanical ventilator may be replaced with an air bag if a mechanical ventilator is not available.

[0037] The proximal end 104 is the end of the tracheal tube system that is not intubated inside the patient. In this specification, to intubate a patient refers to placing a tube in the patient. For example, intubating a patient may refer to the inserting a breathing tube into the trachea for mechanical ventilation. The proximal end 104 is open and connected to the end of the connector 102 opposite the mechanical ventilator. In an embodiment, the proximal end 104 has a length of 31 cm. In an embodiment, the proximal end 104 is made from flexible polyvinylchloride.

[0038] The catheter 106 is a tube that is inserted into the body in order to aid delivery of medications. The catheter 106 may be inserted into the trachea to deliver oxygen. The catheter 106 may be made from a tube. The catheter 106 may be made out of plastic (e.g., polyvinyl chloride, PVC). The plastic materials may be visually clear or opaque. Since plastic is not radio opaque, the catheter 106 may have a line of radio opaque material that makes the tube more visible on a chest X-ray. In other embodiments, the catheter 106 may be made out of wire-reinforced silicone rubbers. Yet in other embodiments, the catheter 106 may be made out of silicone rubber, latex rubber, or stainless steel. The different materials used to make a tracheal tube usually depend on the application of the tube that is required. For example, a wire-reinforced silicone rubber catheter is quite flexible yet difficult to compress or kink, making the wired-reinforced silicone rubber catheter useful for situations in which the trachea is anticipated to remain intubated for a prolonged duration, or if the neck needs to remain flexible during surgery.

[0039] The catheter 106 may have an inner diameter and an outer diameter. The "size" of a tracheal tube refers to the inner diameter of the catheter. For example, if someone asks for a "size 6" tracheal tube, they are asking for a tracheal tube with an inner diameter of 6 mm. Furthermore, the inner diameter may be labeled on the catheter 106 as "ID 6.0." Narrower tubes increase the resistance to gas flow. For example, a size 4 mm tube has sixteen times more resistance to gas flow than a size 8 mm tube. The additional resistance can be especially relevant in the spontaneously breathing patient who will have to work harder to overcome the increased resistance. Therefore, when choosing the appropriate "size", the largest size that is suitable for a given patient is typically recommended. For human beings, the size of the catheter 106 may range from 2.0 mm for neonates to 10.5 mm for adult males. The catheter 106 may have an OD of .7 cm to .9 cm (depending on the size of the patient).

[0040] The catheter 106 may have varying lengths depending on who or what is using the catheter 106. The length of the catheter 106 is measured from the end that goes into the trachea. The length of the catheter may vary if the catheter 106 is inserted orally or through the tracheostomy stoma. For human beings with an oral insertion, the length

of the catheter 106 may range from 7.5 cm for neonates to 23 cm for adult males. In an embodiment, the catheter 106 may be inserted orally or nasally as an endotracheal tube.

[0041] In another embodiment, the catheter 106 may be inserted into a tracheostomy stoma and used in a tracheostomy. A tracheostomy is an opening through the neck into the trachea through which a tube may be inserted to maintain an effective airway and help a patient breathe. A tracheostomy stoma is the actual opening. When the catheter is used in a tracheostomy, the length of the catheter 106 may be shorter.

[0042] The primary channel 107 is the main passageway of the catheter 106 for delivering gases containing oxygen to a patient or for extracting carbon dioxide (CO_2) from a patient. The OD of primary channel 107 is variable from .6 cm to .8 cm. In an embodiment, the diameter of the primary channel 107 is the same as the inner diameter of catheter 106.

[0043] The suction device 108A is a machine that can be used to remove mucous and other unwanted fluids from a patient. The suction device 108A creates a negative pressure in order to extract mucous and other unwanted fluids from a patient. The suction device 108A may have a varying power of suction. The suction device 108A may run continuously at a low power of suction setting to provide a constant suction. The suction device 108A may run on a periodic or as needed basis, depending on the situation of application.

[0044] The air dispenser device 108B is a machine that can be used to pump air or other gases as well as aerosolized agents (e.g., pharmaceuticals). The air dispenser device 108B may be an electronically powered air dispenser or a manual air pump such as a syringe filled with air.

[0045] The fluid dispenser device 108C is a machine that is used to pump fluid. The fluid dispenser device 108C may be an electronically powered fluid dispenser with varying or fixed power of dispensing. The fluid dispenser device 108C may also be a manually operated device such as a syringe filled with a fluid.

[0046] The fluid reservoir 108D is a reservoir for storing rinsing fluid to dispense into a patient to help loosen mucous build up to allow for an easier extraction. The fluid reservoir may be water to be used as a cleaning agent and/or may include another cleaning agent, or may be saline or an antibiotic rinse. The fluid reservoir 108D may be the fluid source for the fluid dispenser device 108C. In some embodiments, fluid dispenser device 108C may not need to draw from the fluid reservoir of 108D.

[0047] The suction tube 108E is a tube adapted to suction secretion collected inside the border of the cuff and trachea region around the tracheal tube. The border of the cuff and trachea region is the part of the cavity of the larynx below the true vocal chords. The suction tube 108E may be adapted to connect to a suction device to suction the secretion. In some embodiments, the suction tube 108E may be attached to the catheter 106 proximal to the open proximal end 104. In other embodiments, the suction tube 108E may extend into the inner walls of the catheter 106. The suction tube 108E length is 24 cm. The suction tube 108E may be made from flexible polyvinylchloride.

[0048] In another embodiment, the suction tube 108E may be adapted to connect to an air dispensing device 108B to dispense air into the suction tube 108E to clear out the suction tube.

[0049] In yet other embodiments, the suction tube 108E may be adapted to connect to a fluid dispenser device 108C to provide a rinsing fluid. The fluid dispenser device may draw the rinsing fluid from the fluid dispensing reservoir 108D. The purpose of the rinsing fluid may be to loosen up the secretion and mucous surrounding the border of the cuff and trachea region around the trachea to loosen mucous, which may collect around the tracheal tube. Once the rinsing fluid has been introduced, suction may be restored to the suction tube 108E and the liquid and any secretions that may have been loosened or dissolved may be removed. The introduction of a rinsing fluid procedure may be repeated as deemed necessary and it is performed at the discretion of the caregiver or user in order to clean secretions and other liquids that may collect and potentially clog the suction. The rinsing fluid may comprise water, saline, as well as other biocompatible liquids or mucolytic agents. A mucolytic agent is an agent, which dissolves thick mucus and is usually used to help relieve respiratory difficulties. It does

so by dissolving various chemical bonds within secretions, which in turn can lower the viscosity by altering the mucin-containing components.

[0050] The inflation tube 110A is a tube used to supply an inflation fluid. In an embodiment, the inflation tube 110A length is 24 cm. In an embodiment, the inflation tube is made from flexible polyvinylchloride.

[0051] The pilot balloon 110B is a balloon that provides an indication of the air pressure that exists in another balloon that it is connected to. Furthermore, the pilot balloon 110B has a one-way valve that prevents air inflated into the pilot balloon 110B from deflating because of the one-way valve design. The pilot balloon 110B may serve as a balloon deflator when the pilot balloon 110B is pressed, thus turning the one-way valve into a two-way valve.

[0052] The inflation fluid supplying device 110C is a device that delivers an inflation fluid. The inflation tube 110A may be connected to the inflation fluid supply device 110C by way of pilot balloon 110B. The fluid supplying device 110C may be a syringe or a pump. The inflation fluid may be a gas or a liquid, depending on the desired functionalities of the inflation fluid. The inflation fluid may be air. The inflation fluid may also be a methylene blue colored saline. For example, some airway surgery involves the use of laser beams to burn away tissue. These beams can ignite ordinary endotracheal tubes and in the presence of Oxygen may cause major airway fires. If the laser manages to damage the balloon, the coloring will help identify rupture and the saline will help prevent an airway fire.

[0053] The suction tube lumen 112 is an extension of the suction tube 108E that extends along the length of the catheter 106. The suction tube lumen 112 further provides suction to the tracheal tube from the suction tube 108E. The suction tube lumen 112 may be connected to the suction tube 108E or it may be an extension of suction tube 108E that is connected to the catheter 106. The suction tube lumen 112 may also extend along the length and inside the walls of catheter 106. In another embodiment, the suction tube lumen 112 may attach to the exterior surface of the catheter 106 and extend along the length of the catheter 106. In other embodiments, the suction tube lumen 112 may provide rinsing fluids from the suction tube 108E.

[0054] The inflation tube lumen 114 is an extension of the inflation tube 110 that extends along the length of the catheter 106. The inflation tube lumen 114 may be connected to the inflation tube 110. The inflation tube lumen 114 may also be an extension of the inflation tube 110 that extends along the length and inside the wall of the catheter 106. In another embodiment, the inflation tube lumen 114 may attach to the exterior surface of the catheter 106 and extend along the length of the catheter 106.

[0055] The suction lumen exit point 116 is the point where the suction lumen 114 emerges from the catheter 106. The suction lumen exit point 116 is strategically located along the length of the catheter 106 so that it is proximal to the location where secretion accumulates in the region bordering the cuff and trachea above the balloon.

[0056] The balloon 118 is an inflatable resilient cuff. The balloon 118 serves as a seal between the tracheal tube and the patient's trachea wall to allow for positive pressure ventilation. Positive pressure ventilation is mechanical ventilation in which air is delivered into the airways and lungs under positive pressure, usually via an endotracheal tube, producing positive airway pressure during inspiration. The balloon 118 may be made from various compositions of rubber or elastic polymer polyurethane. The thickness and elasticity of the rubber material may vary, depending on the intended use of the balloon 118/tracheal tube system 100. In an embodiment, the balloon 118 is 5 cm long and 3 cm in diameter. Excluding rare errors in calcium metabolism, most human male and female trachea diameters fall between 25-29 mm and 23-27 mm, respectively. In an embodiment, the seal between each chamber is not complete so as to allow air to flow from one balloon to the next (the opening between chambers may be the width of the balloon and between 0.1-0.5cm high). In some embodiments, the balloon 118 may be a high pressure, low volume balloon. In other embodiments, the balloon 118 may be a low pressure, high volume balloon. Depending on the intended purpose and use of the balloon, the appropriate material is used. When introduced into the patient, the balloon 118 is initially deflated. Once the tracheal tube system 100 is placed inside the patient's trachea, the inflation tube 110 may be adapted to a fluid supplying device to inflate the balloon 118. The balloon 118 is connected to the inflation lumen 114. Once the balloon 118 is inflated, the shape and expanded size of the balloon 118 creates a seal against the tracheal wall, thereby preventing gases being pumped into

the lungs via the catheter 106 from backing up around the tube and escaping through the tracheal tube, thereby providing a positive pressure ventilation. The inflation of the balloon 118 creates a seal to provide a positive pressure necessary to artificially ventilate the lungs.

[0057] The balloon 118 is attached to the catheter 106 between the suction lumen exit 116 and the distal end 122. The balloon 118 is completely sealed to the catheter 106 at the end of the balloon distal to the suction lumen exit 116. However, the opposite end of the balloon 118 is not sealed to the catheter 106. Instead, the balloon 118 proximal to the open distal end 122 is cylindrical shaped. The balloon, when not attached to a tracheal tube resembles the shape of a bottle without the bottom portion of the bottle. The shape of the balloon is created by the balloon's circular chambers and the size of chambers can vary, the largest balloon is first and the size of the balloons decreases along the direction going towards the lungs. For example, in an embodiment, the balloon 118 diameters of the chambers, in order from proximal to distal, are 3cm, 1 cm, .6 cm, .4 cm, .2 cm, and .1 cm, respectively.

[0058] In another embodiment, the balloon 118 may extend from the open distal end 122 along the length of catheter 106 and ending proximal to the connector 102.

[0059] Tracheal tubes with balloon 118 may present a problem in that secretions produced above the balloon 118 may be prevented from flowing along the channel of the esophagus or trachea and thereby collect above the balloon 118, providing a site for the possible accumulation of pathogens. Occasionally, these pathogens may find their way through the cuff created by balloon 118 and end up below the cuff near the open distal end 122. Once the pathogens make it through the balloon 118, the pathogens may find their way into the patient's lungs and create harmful infection. The accumulation of secretion above the balloon 118 may present other problems as well.

[0060] The suction line 120 is a tube with small holes distributed along a sidewall of the tube. It is important to note that holes are only through one sidewall of the suction line 120, as opposed to being through both sidewalls of the suction line 120. The holes may be distributed in any appropriate arrangement and may be, for example, arranged in a clustered or evenly distributed manner. Sidewalls of the holes may form

any appropriate shape, such as a V-, U-, or square-type shape. An opening in the suction line 120 formed by the holes may be of any appropriate shape, such as, but not limited to a circle, an oval, a square, a rectangle or any combination thereof. In an embodiment, the suction line 120 is 1 cm in length. The small holes allow the suction and removal of secretion fluid that comes in contact with the suction line 120. The suction line 120 may be an extension of the suction tube 108E and the suction tube lumen 112. The suction line 120 emerges from within the catheter 106 walls at the suction lumen exit point 116. The connection point between the balloon 118 and the catheter 106 proximal to the suction line 120 may be .5 cm – 1.5 cm above the balloon 118 to ensure a secure seal of the balloon 118 to the catheter 106. The suction line 120 is wrapped around the catheter 106 and above the balloon 118. The suction line 120 wrap provides a 360 degree suction of secretion fluids that collect in the space above the balloon 118 and within the patient's trachea (area bordered by the cuff and trachea) without negatively impacting ventilation of the patient at the level of the cuff suction line attached to balloon.

[0061] The suction line 120 may also wrap around the balloon 118. The suction line 120 may wrap around the balloon 118 multiple times before terminating at a distal point of the exterior surface of balloon 118. The suction line 120 provides suction of secretions that collect in the spaces between the balloon 118 and the patient's trachea. The suction line 120 may also provide additional sealing properties between the balloon and the tracheal wall within the patient when there is negative pressure within the suction line 120.

[0062] The suction line 120 may also coil around the balloon 118 within predefined sleeves on the balloon 118 outer surface. The sleeves will be further discussed in FIGs. 5 and 12C.

[0063] In other embodiments, the suction line 120 may also distribute a rinsing fluid when the suction tube 108E is adapted to connect to a fluid dispensing device to dispense a rinsing fluid. The rinsing fluid flows through the small holes dispersed along the suction line 120.

[0064] The open distal end 122 is the opening at the end of the tracheal tube system 100. In most embodiments, the open distal end 122 is the end that resides inside

the patient's tracheal area and the open distal end 122 is where the mechanical ventilator's air, traveling through the primary channel 107, may enter the patient's lungs. When the tracheal tube system 100 is intubated inside a patient, the open distal end 122 of the catheter 106 is situated within the upper respiratory system of the patient. In current use, the open distal end 122 serves as the primary air passage way for mechanically ventilating a patient, with an opening in the sidewall of catheter 106 as the secondary source of air passage in the event the open distal end 122 is blocked. In the current embodiment, the open distal end 122 will still serve as an air passage way.

[0065] The enlarged opening 124 provides an alternative air flow source to the patient's lungs in the event the open distal end 122 is blocked or obstructed. The enlarged opening 124 serves as the primary source of air flow into the patient's lungs since the enlarged opening 124 has an opening considerably larger than the open distal end 122. The airflow from enlarged opening 124 comes into contact with the interior layer of the balloon 118. The inflated balloon 118 creates a cuff along the tracheal wall to prevent the escape of air pressure between the patient's lung and the tracheal tube system 100. The airflow that comes out of the enlarged opening 124 may flow around the inner layer of the balloon 118 and get redirected towards the patient's lung. The enlarged opening 124 may have a length that is slightly longer along the length of the catheter 106 than the balloon 118 such that the opening 124 may start from a point proximate to the 360 degree seal of the balloon 118 with the catheter 106 proximal to the suction lumen exit 116 and extend beyond the point where the balloon 118 ends proximal to the distal end 122. The width of the enlarged opening 124 may be adjusted to create a larger cross sectional area of air flow to travel between the patient's lungs and the catheter 106.

[0066] In another embodiment, where the length of the balloon 118 may extend from proximal to the open distal end 122 along the length of catheter 106 and terminate proximal to catheter opening 104, the length of the enlarged opening 124 may extend along the length of the entire catheter 106 to provide a larger amount of area for airflow to travel between the primary channel 107 and the patient's lungs.

[0067] The enlarged air passage way 126 is a passage way through which fluids pass between the patient's trachea and the tracheal tube system 100. A size of the enlarged air passage way 126 may be determined by taking the cross-sectional area measured by the inner diameter of the inflated balloon 118 and subtracting the cross-sectional area of the catheter 106. The enlarged air passage way 126 allows the same amount of air volume to move into the patient's lungs but at a slower velocity as compared to prior devices.

[0068] The velocity at which a volume of air flows through a pipe may be increased or decreased based on the diameter of the pipe. Decreasing the input velocity increases particle size, decreases the aerosolization, and decreases micro speciation. The diameter of the pipe defines the cross-sectional area available for the volume of air to flow through. The velocity of a volume of air flows through a passage way may be reduced if the diameter of the passage way is increased. Likewise, when the diameter of the passage way is reduced, to move the same fixed volume of air through the reduced diameter passage way, the velocity at which the volume of air flows must be increased to move the same fixed volume of air through the reduced diameter passage way. The increased diameter of the passage way will increase the cross-sectional area for air to travel through. With a larger cross-sectional area for air to travel through the tracheal tube system 100 based on the enlarged air passage way 126 created by the shape of the balloon 118 proximal to the open distal end 122, the same volume of air that needs to flow into the lung(s) at the enlarged air passage way 126 may be delivered to the lung(s) at a reduced velocity. The volume of air that flows through from the enlarged opening 124 located within the balloon 118 is delivered to the lungs through the enlarged air passageway 126. The reduction in velocity of airflow at the enlarged air passage way 126 helps to address a common cause of issues with tracheal procedures, such as Ventilator Associated Pneumonia (VAP). VAP can be minimized by eliminating the "aerosolization" of foreign bodies that shoot into the lower area of the lungs from the high speed of the ventilator. Currently, the "aerosolization" of foreign bodies traveling at high velocity into the lungs is due to the small cross sectional area of the traditional tracheal tube. The smaller the cross sectional area of the tube, the higher the velocity is required to move the same volume of air. The enlarged air passage way 126 may allow

the appropriate amount of air to travel into the patient's lungs at a reduced velocity of airflow that, in turn, may help to reduce a number of pathogens delivered to the lungs, which may cause VAP. In an embodiment, the length of the air passage way 126 is 4.5 cm, whereas in contrast a standard Murhpy's Eye is 1.0 to 1.5 cm.

[0069] FIGs. 2A and 2B show a diagram similar to that of FIG. 1 but illustrating other embodiments of a tracheal tube. The tracheal tube system 200A and 200B may include the following elements, as explained in FIG. 1, at least one connector 102, a catheter 106 having opposed open proximal end 104 and open distal end 122, a suction device 108A, an air dispenser device 108B, a fluid dispenser device 108C, a fluid reservoir 108D, at least one suction tube 108E, at least one inflation tube 110A, a pilot balloon 110B, an inflation fluid supplying device 110C, at least one suction line 120, a plurality of enlarged opening 124, at least one enlarged air passage way 126, and at least one balloon 218a (FIG. 2A) or 218b (FIG. 2B). In other embodiments the tracheal tube system 200 may not have all of the elements or features listed and/or may have other elements or features instead of or in addition to those listed.

[0070] Furthermore, the tracheal tube system 200A and 200B may also include a vocal chord crease 202. The vocal chord crease 202 is a portion of the balloon 118 that is narrow and extends for an amount necessary to clear the vocal chords of the patient. The purpose of the vocal chord crease 202 is to minimize contact between the tracheal tube system 200 and the patient's vocal chord. The balloon 218a or 218b in the current embodiment extends along approximately the entire length of the catheter 106. Other than the length of the balloon 218a or 218b and the crease in the balloon 218a or 218b at the vocal chord crease 202, the balloon 218a or 218b is essentially the same as the embodiment described in FIG. 1. No balloons are located in the crease to avoid direct pressure on the vocal chords. The crease is suspended off the vocal cords by balloons on either end of the crease, and in an embodiment, the crease is color coded so that medical personnel can see where to position the crease.

[0071] The plurality of the enlarged openings 124 is the primary air flow channel for the ventilation of the patient. The plurality of the enlarged openings 124 allows the velocity of the airflow between the patient's lungs and the tracheal tube system 200 to be

comparable to the velocity of the airflow the patient would experience without an artificial ventilation system.

[0072] In an embodiment, balloon 218a or 218b forms a tube surrounding and attached to catheter 106, which is open at both ends, so that air may enter one end of the tube formed by balloon 118 and exit the other end of the tube formed by balloon 218a or 218b. When one end of endotracheal tube system 200A or 200B is placed within a patient, air may enter the patient via both the tube formed by balloon 218a or 218b, respectively, and catheter 106, so that air may enter and travel into the patient through a larger cross sectional area than were balloon 218a or 218b not present or crossed.

[0073] Endotracheal tube systems 200A and 200B differ from one another in that the sections of balloon 218a all have the same diameter, whereas the sections of balloon 218b have decreasing diameters. In an embodiment, the largest segment of balloon 218b has an outer diameter 5 cm, the narrowest segment has an outer diameter of 1.5 cm, and the segments in between monotonically decrease in diameter from 5 cm to 1.5 cm going form the end of the endotracheal tube 200B that is furthest from the lungs toward the end that is closest to the lungs.

[0074] FIG. 3 shows a cross-sectional view 300 of an embodiment of the catheter of FIG. 1 taken longitudinally through the catheter at 3—3. The cross-sectional view 300 may include an exterior surface 302, an interior surface 304, a wall thickness 306, a catheter 106, suction lumen 112, inflation lumen 114, and primary channel 107.

[0075] The catheter 106, suction lumen 112, inflation lumen 114, and primary channel 107 were discussed with regard to FIG. 1. The exterior surface 302 is the exterior surface of catheter 106. The interior surface 304 is the interior surface of the catheter 106. The wall 306 is the tube thickness determined by the exterior surface 302 and the inner surface 304. The thickness of the wall 306 may vary based on the different uses and application of the tracheal tube system 100.

[0076] The suction lumen 112 may be an extension of the suction tube 108E (from FIG. 1) wherein the suction lumen 112 is configured to run along the inside of the

wall 306. In another embodiment, the suction lumen 306 may be attached to run along the exterior surface 302 of the catheter 106.

[0077] The inflation lumen 114 may be an extension of the inflation tube 110A (from FIG. 1) wherein the inflation lumen 114 is configured to run along the inside of the wall 306. The inflation lumen 114 may be situated opposite the suction lumen 112. In another embodiment, the inflation lumen 114 may be configured to run along the exterior surface 302 of the catheter 106.

[0078] FIG. 4 shows a cross-sectional view 400 of an embodiment of a catheter 106 and a balloon 118 of FIG. 1 taken longitudinally through the catheter 106 and the balloon 118 at 4—4. The cross-sectional view 400 may include a spinal sealant 402, a balloon inner layer 404, a balloon thickness 406, and a catheter 106. Furthermore, cross-sectional view 400 may also include a primary channel 107, a balloon 118, a suction line 120, and an enlarged airway passage 126; all of which are further defined in FIG. 1.

[0079] The spinal sealant 402 is the contact point along the outer surface of the catheter 106 and the inner surface of balloon 118. The balloon inner layer 404 is the inner layer of the balloon 118. The balloon thickness 406 is the thickness of the balloon 118 when fully inflated. The balloon thickness 406 may be a variable in the enlarged airway passage 126. The thicker the balloon, the smaller the enlarged airway passage. Likewise, the thinner the balloon thickness 406, the larger the enlarged airway passage 126. The balloon thickness 406 may vary to provide the appropriate amount of enlarged airway passage 126. The spinal sealant 402 is designed to not have any contact with the enlarged opening 124.

[0080] The spinal sealant 402 connection point may extend the length of the catheter 106 (which is situated inside the balloon 118) to create a secure attachment between the balloon 118 and the catheter 106. In an embodiment, the spinal sealant 402 may be located opposite the enlarged opening 124 located on the catheter 106, so that the enlarged opening 124 is not in contact with the inner wall of the balloon 118. The spinal sealant 402 may be glued to the inner walls of balloon 118. In another embodiment, the spinal sealant 402 may be heat infused by melting the inner wall of the balloon 118 along the spinal sealant 402 together. The airflow that comes out of the enlarged Murhpy's

Eye will travel through the catheter 106 by way of the primary channel 107 and exit the catheter 106 in one of two locations: 1) at the open distal end 122 or 2) at the enlarged opening 124. The air exiting the enlarged opening 124 eventually flows through the enlarged air passage way 126.

[0081] FIG. 5 shows an embodiment of the balloon assembly 500. The balloon assembly 500 may include an outer balloon sheet 502, a plurality of sleeves 504, an inner balloon sheet 506, a tube connection point 508, a distal edge 510, and an inflation connection point 512.

[0082] The outer balloon sheet 502 is the exterior layer of the balloon 118 that comes into contact with the patient's tracheal walls. The outer balloon sheet 502 is generally a rubber material with various thickness and elasticity, depending on the application of the balloon. For example, the balloon 118 may be adapted to be used in as a low volume, high pressure cuff or a high volume, low pressure cuff. In a low volume, high pressure application, the material of the balloon may be slightly thicker and less elastic whereas in a high volume, low pressure application, the material may be thinner and more elastic.

[0083] The plurality of sleeves 504 are like channels arranged parallel to one another in a diagonal configuration with respect to the outer balloon sheet 502. The sleeves 504 are aligned diagonally in such a way that when the outer balloon sheet 502 is curled into a cylindrical shape, the sleeves 504 line up at the connection point to create a single helical groove around the cylindrical shape of the outer balloon sheet. Once the sleeves 504 are aligned, the sleeves may allow the suction line 120 to wrap around the balloon 118 in an organized and predictable form because the suction line 120 fits neatly into the sleeves. Once the suction line 120 is wrapped around the balloon 118 within the sleeves 504, the suction line 120 may provide a slight protrusion over the balloon surface. The protrusion provides a more secure and stable seal between the balloon 118 and the patient's tracheal wall because the suction effect created by the suction line 120 around the balloon 118 helps to securely seal the balloon with the tracheal walls.

[0084] The inner balloon sheet 506 is the inner layer of the balloon 118. The inner balloon sheet 506, when attached to the outer balloon sheet 502, allows the balloon

118 to take form. The tube connection point 508 is the portion of the balloon 118 that attaches the balloon 118 to the tracheal tube. The tube connection point 508 is the only portion of the balloon 118 that attaches to the tracheal tube. The attachment is a 360 degree tight seal around the tube. When the outer balloon sheet 502 and inner balloon sheet 506 are attached, the tube connection point 508 is sealed tight to not allow any air to travel in between the two sheet because the purpose of the connection point 508 is attach the balloon 118 to the tracheal tube.

[0085] The distal edge 510 is the edge of the outer balloon sheet 502 and inner balloon sheet 506 that is opposite the tube connection point 508. The distal edge 510 is the section of the outer and inner balloon sheets that is sealed together to create a balloon shape.

[0086] The longitudinal edge 512 is the edge that runs along the balloon longitudinally. One end of the edge is the distal edge 510 and the other end of the edge is the connection point 508. The longitudinal edge 512 of the inner balloon sheet 506 will be the edge that seals to the opposing longitudinal edge 512 of the inner balloon sheet 506 to create a cylindrical shape for the inner balloon sheet 506. Likewise, the longitudinal edge 512 of the outer balloon sheet 502 will be the edge that seals the opposing longitudinal edge 512 of the outer balloon sheet to create a cylindrical shape for the outer balloon sheet 502. The outer balloon sheet 502 is slightly larger than the inner balloon sheet 506 so that the cylindrical shape of the outer sheet may fit on the outside of the cylindrical shape of the inner sheet. The sleeves 504 are outward facing on the outside of the outer balloon sheet's cylindrical form.

[0087] The inflation connection point 512 is where the balloon's inflation fluid enters and exists to inflate and deflate the balloon 118 respectively. The inflation connection point 512 connects to the inflation lumen 114 (FIG. 1). The inflation connection point 512 may be a hole or it may be an actual small valve connector to connect to the inflation lumen 114. In other embodiments, it may just be a marking on the inner balloon sheet to provide guidance to create a hole upon assembly and attachment of the balloon 118 to the catheter 106.

[0088] The sleeves 504 on the balloon 118 will create a channel to allow the suction line wrap 114 to remain securely attached to the balloon 118. Once the balloon 118 is inflated, the suction line wrap 114 fits securely in the helical sleeve 504 (FIG. 5) on the balloon 118. The suction line wrap 114 provides a slight protrusion over the balloon surface to provide a more secure and stable seal of the balloon and the tracheal tube system 100 within the patient because the slight protrusion is that of the suction line wrap 114. The suction effect created by the suction line wrap 114 around the balloon 118 helps to securely seal the balloon with the tracheal walls

[0089] The balloon 118 is shaped by fusing the two layers of the balloon sheets together where the outer balloon sheet 502 will have a sleeve 504 to allow the suction line 120 to lie within. One end of the balloon 118 is completely sealed to the catheter 106 proximal to suction line 120. The other distal end of the balloon will not be completely sealed to the catheter 106. Instead, the inner balloon layer 506 will be attached to the spine portion of the catheter 106 as displayed as the spinal sealant 402 (FIG. 4).

[0090] FIG. 6A shows a flowchart of an embodiment of method 600a in which a caregiver is intubating a patient. Initially, the caregiver determines that a patient needs an advance airway orally and then, in step 604, the caregiver opens the patient's mouth to begin the intubation process. In step 606, the caregiver pushes the patient's jaw forward to create an adequate opening to perform the intubation.

[0091] In step 608, the caregiver may use a laryngoscope as a guide to place the endotracheal tube above the epiglottis. The caregiver may also use a glideslope to assist with the intubation process. In some situations, where no guiding tools are available, the caregiver may intubate blindly if the situation requires immediate intubation. A laryngoscope is a medical device that is used to obtain a view of the vocal folds and the glottis. Laryngoscopy (larynx + scopy) may be performed to facilitate tracheal intubation. A glidescope is the first commercially available video laryngoscope. The glidescope incorporates a high resolution digital camera, connected by a video cable to a high resolution LCD monitor. It may be used for tracheal intubation to provide controlled mechanical ventilation. When using the laryngoscope or glidescope to

facilitate intubation, the caregiver should exercise special care to identify the vocal chords in order to properly intubate the tracheal tube to prevent contact between the balloon 118 and the vocal chords. If the caregiver does not properly intubate the tracheal tube below the vocal chord and if upon inflation of the balloon 118 the cuff expands onto the vocal chord, it may damage the patient's vocal chords. Extra care must be exercised to ensure the intubation is performed correctly and the vocal chords are clear of contact by the balloon once the balloon 118 is inflated. An aluminum stylet may be used to provide the flexible endotracheal tube with some support and stiffness to assist with the intubation process.

[0092] In step 610, the caregiver places the tracheal tube into place properly without causing injury. Injuries may include breaking teeth or damaging vocal chords and would not include trauma that may be expected with the intubation process. In step 612, once the intubation is complete, the caregiver removes the aluminum stylet from the tracheal tube.

[0093] In step 614, the caregiver inflates the balloon with air by attaching a syringe or any other fluid providing device that may be required to inflate the balloon. In some embodiments, air may be the fluid of choice. In other embodiments, a liquid based fluid may be used. When the balloon is inflated, the coiled suction line 120 form fits into the sleeves on the outside of the balloon.

[0094] In step 615, the caregiver deploys the suction line 120 and the balloon is inflated to the tracheal border.

[0095] In step 616, the caregiver connects the suction tube 108E to a suction device 108A to provide a constant stream of suction to the region bordered by the cuff and trachea above the balloon 118. The suction device may have a suction power adjustable knob to set a desired suction. By connecting the suction tube 108E to the suction device 108A, the removal of secretion build up located above the balloon 118 and between the tracheal walls and the balloon may continue indefinitely without the need for a caregiver to constantly monitor the patient for secretion build up.

[0096] In step 617, the suction line 120 creates a seal between the balloon 118 and the trachea.

[0097] In an embodiment, each of the steps of method 600a is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 6A, steps 604-617 may not be distinct steps. In other embodiments, method 600a may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 600a may be performed in another order. Subsets of the steps listed above as part of method 600a may be used to form their own method.

[0098] FIG. 6 shows a flowchart of an embodiment of method 600b in which a caregiver is removing an endotracheal tube. In step 652, the caregiver deflates the balloon 118 by pressing the pilot balloon 110B. In step 654, the caregiver carefully removes the endotracheal tube from the patient orally.

[0099] In an embodiment, each of the steps of method 600b is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 6B, step 652-654 may not be distinct steps. In other embodiments, method 600b may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 600b may be performed in another order. Subsets of the steps listed above as part of method 600b may be used to form their own method.

[00100] FIG. 7A shows a flowchart of an embodiment of method 700a in which a suctioning device is suctioning secretion from the region bordered by the cuff and trachea. In step 702, the suction tube 108E is connected to a suction device 108A. In step 704, the negative pressure within the suction tube 108E is transferred through the suction tube lumen 112 to the suction line 120. In step 706, the negative pressure creates a negative pressure / suction at the suction holes throughout the suction line 120. In step 708, the accumulated secretions are suctioned through the suction holes for disposal. In step 710, the negative pressure within the suction line creates a seal between the balloon 118 and the patient's tracheal wall. The secretions may be collected for samples for culture for diagnosing and monitoring.

[00101] In an embodiment, each of the steps of method 700a is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 7A, step 702-710 may not be distinct steps. In other embodiments, method 700a may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 700a may be performed in another order. Subsets of the steps listed above as part of method 700a may be used to form their own method.

[00102] FIG. 7B shows a flowchart of an embodiment of method 700b in which a rinsing fluid dispensing device is applying a rinsing fluid. In step 742, the suction tube 108E is connected to a rinsing fluid device 108C. In step 744, the rinsing fluid travels through the suction tube 108E, the suction tube lumen 112, and the suction line 120. In step 746, the rinsing fluid is dispersed through the suction holes on the suction line 120. The rinsing fluid is allowed to momentarily interact with the mucous and area bordered by the cuff and trachea. Depending on the rinsing fluid used, the mucous may be loosened to allow it to be easily extracted. In step 748, the suction tube 108E is reconnected to a suction device 108A to remove the rinsing fluid and any other secretion that may have collected during the rinsing fluid administering process.

[00103] In an embodiment, each of the steps of method 700b is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 7B, step 742-748 may not be distinct steps. In other embodiments, method 700b may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 700b may be performed in another order. Subsets of the steps listed above as part of method 700b may be used to form their own method.

[00104] FIG. 7C shows a flowchart of an embodiment of method 700c in which a mechanical ventilator is artificially ventilating a patient. In step 762, a tracheal tube system 100 is connected to a mechanical ventilator via connector 102. In step 764, the mechanical ventilator pumps air to and from the patient's lung(s) by way of a primary channel 107, the enlarged opening 124, and the open distal end 122. The velocity of oxygen and air flowing into the patient's lungs is reduced as a result of the enlarged opening 124 and the enlarged air passage way 126.

[00105] In an embodiment, each of the steps of method 700c is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 7C, step 762-764 may not be distinct steps. In other embodiments, method 700c may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 700c may be performed in another order. Subsets of the steps listed above as part of method 700c may be used to form their own method.

[00106] FIG. 8 shows a flowchart of an embodiment of method 800 in which a tracheal tube of system 100 is manufactured. In step 802, a tracheal tube is made. In step 804, a balloon 118 is made, which involves the step of making the balloon 118. In step 806, the balloon 118 is attached to the tracheal tube from step 802. In other embodiments of method 800, step 804 may be performed before step 802. However, step 806 requires that step 802 and step 804 be performed in order to attach the tracheal tube and the balloon 118.

[00107] In an embodiment, each of the steps of method 800 is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 8, step 802-806 may not be distinct steps. In other embodiments, method 800 may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 800 may be performed in another order. Subsets of the steps listed above as part of method 800 may be used to form their own method.

[00108] FIG. 9 shows a flowchart of an embodiment of a method for implementing step 802 in which a tracheal tube system 100 is manufactured. In step 902, a tracheal tube is made, which may include making a catheter 106 from a plastic (polyvinyl chloride, PVC) material with 3 lumen comprising a suction lumen 108E, an inflation lumen 110A and a primary channel 107. In other embodiments, other types of material may be used to make the catheter 106 such as wire-reinforced silicone, silicone rubber, latex rubber, or stainless steel. The length, diameter, and thickness of the catheter 106 may vary depending on the size of the catheter being created for the various ages, genders and sizes of a targeted user base. The suction lumen 108E and inflation lumen 110A are built into the wall of the catheter 106. In other embodiments, the

suction lumen 108E and inflation lumen 110A may be tubes attached on the outer surfaces of catheter 106.

[00109] In step 904, make a suction lumen exit 116. The suction lumen exit 116 is an exit hole at the distal end of the suction lumen 108E proximal to the balloon 118. The suction lumen exit 116 may be located slightly above the point where the balloon 118 will be attached to the catheter 106.

[00110] In step 906, a bevel cut is made at open distal end 122. The bevel shape of the catheter 106 helps with the intubation process of the tracheal tube.

[00111] In step 908, an enlarged opening 124 is made. Step 908 involves cutting an elongated oval shaped opening proximal to the open distal end 122 on the top side of the catheter 106. The length of the enlarged opening 124 is extended along the length of the catheter 106 starting proximal to the open distal end 122 and extending proximal to the suction lumen exit hole 116.

[00112] In step 910, an inflation tube 110A, suction tube 108E, and suction line 120 is attached to the catheter 106. An inflation tube 110A is attached to the inflation lumen 114 on one end and to a pilot balloon 110B on the opposite end. In another embodiment, inflation tube 110A may be an extension of inflation lumen 114 and a part of step 902. In other embodiments, pilot balloon 110B may be attached to the inflation tube prior to intubation.

[00113] A suction tube 108E is attached to the suction tube lumen 112. In another embodiment, suction tube 108E may be an extension of suction tube lumen 112 and a part of step 902.

[00114] A suction line 120 is attached to the suction lumen exit 116. The suction line 118 may be similar to the suction tube 108E in material, shape, and diameter. However, the suction line 120 contains many small holes distributed throughout the suction line 120 in order to provide fluid transmission in and out of the suction line 120. In another embodiment, the suction line 120 may be an extension of the suction lumen 112 and a part of the suction lumen exit 116.

[00115] In step 912, a preformed balloon cuff is attached to the balloon 118.

[00116] In an embodiment, each of the steps of method 802 is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 9, step 902-912 may not be distinct steps. In other embodiments, method 802 may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 802 may be performed in another order. Subsets of the steps listed above as part of method 802 may be used to form their own method.

[00117] FIG. 10 shows a flowchart of an embodiment of a method of implementing step 804 in which a balloon is manufactured. In step 1002, an outer balloon sheet 502 is made using a flexible rubber based thin sheet that is generally used in balloon manufacturing for endotracheal tubes. The outer balloon sheet 502 comprises a plurality of sleeves 504 arranged diagonally across the sheet to serve as channels for the suction line 120 to fit into when the balloon 118 is inflated. The diagonally aligned sleeves on the outer balloon sheet 502, when curled lengthwise and attached, creates a helical groove for the suction line 120. The shape of the outer sheet is displayed in FIG. 5.

[00118] In step 1004, an inner balloon sheet 506 is made using a similar material as the material used in step 1002 when making the outer balloon sheet 502. The inner balloon sheet 506 is the same shape as the outer balloon sheet 502. The inner balloon 506 does not contain sleeves arranged diagonally across the sheet.

[00119] In step 1006, the inner balloon sheet 506 is curled into a cylindrical shape and sealed along the longitudinal edge 512. In step 1008, the outer balloon sheet 502 is curled into a cylindrical shape and sealed along its longitudinal edge 512.

[00120] In step 1010, the outer balloon sheet 502 and inner balloon sheet 506 are sealed to one another along the distal edge 510 and the balloon connection point 508. The outer balloon sheet 502 is on the outside of the connection with the sleeves 504 facing outwards. The balloon connection point 508 is sealed completely to ensure there will be no spaces for air to inflate in connection point 508 area of the balloon assembly.

[00121] In an embodiment, each of the steps of method 804 is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 10, step 1002-1010 may not be distinct steps. In other embodiments, method 804 may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 804 may be performed in another order. Subsets of the steps listed above as part of method 804 may be used to form their own method.

[00122] FIG. 11 shows a flowchart of an embodiment of a method for implementing step 806 in which a balloon is attached to a tracheal tube. The attachment of the balloon 118 assembled from step 804 and tracheal tube assembled from step 802. In step 1102, the balloon 118 is attached to the tracheal tube assembled from step 802 by inserting the distal end 122 through the balloon 118 from the connection point 508 towards the distal edge 510. The connection point 508 is sealed completely around the catheter 106 proximal to the suction lumen exit 116 without coming into contact with the suction lumen exit 116.

[00123] In step 1104, the inner surface of the balloon 118 is sealed to the spinal length of the catheter 106 along the spinal seal 402. The spinal seal 402 does not contact or obstruct the enlarged opening 124. The inflation lumen 114 is connected to the balloon 118 at the inflation connection point 512. In step 1106, the suction line 120 is coiled around the catheter 106 from the suction lumen exit 116 towards the distal end 122. The suction line 120 is further coiled around the deflated balloon 118 guided by the helical groove created by the sleeves 504.

[00124] In step 1108, the suction line 120 is attached to the outer surface of the distal end of balloon 118. The attached point may be proximal along the distal edge 510 of the balloon, without actually coming into contact with the sealed distal edge 510.

[00125] In an embodiment, each of the steps of method 806 is a distinct step. In another embodiment, although depicted as distinct steps in FIG. 11, step 1102-1108 may not be distinct steps. In other embodiments, method 806 may not have all of the above steps and/or may have other steps in addition to or instead of those listed above. The steps of method 806 may be performed in another order. Subsets of the steps listed above as part of method 806 may be used to form their own method.

[00126] FIGs. 12A and 12B illustrate an alternative embodiment of tracheal tube system 100; tracheal tube system 1200. More specifically, FIG. 12A illustrates a side view of tracheal tube system 1200 and FIG. 12B illustrates a front view of tracheal tube system 1200.

[00127] In tracheal tube system 1200, both ends of the balloon 118 are joined to the catheter 106 so that air, or other gasses, does not escape from the balloon 118. The balloon 118 includes an indentation 1210 shaped and positioned to accommodate placement of a portion of suction line 120 thereon. Indentation 1210 may be positioned so as to correspond to a portion of the balloon 118 furthest away from the open distal end 122 and may be sized to accommodate positioning of the suction line 120 circumferentially over an upper portion of an exterior surface of the balloon 118 (i.e., away from the open distal end 122) as shown in FIGs. 12A and 12B. For example, indentation 1210 may be sized so as to accommodate positioning of the suction line 120 circumferentially over 60^{o} – 270^{o} (i.e., 16.7%-75%) of the upper exterior surface of the balloon 118.

[00128] In some embodiments, indentation 1210 may act to guide the shape and/or positioning of the suction line 120 into a desired configuration, while in other embodiments, suction line 120 may be pre-configured by, for example, a molding process, to be shaped to fit within indentation 1210. For illustrative purposes, the indentation depicted in FIGs. 12A and 12B is configured to accommodate a triangular-shaped shaped suction line 120 as described below with regard to FIG. 14A. However, it will be appreciated by those of skill in the art that indentation 1210 may be sized, shaped, and/or positioned to accommodate any number of shaped suction lines 120, such as the exemplary shaped suction lines 120 of FIGs. 14B-14E as described in greater detail below.

[00129] FIG. 13 illustrates an alternative embodiment of the balloon assembly 500; balloon assembly 1300. Balloon assembly 1300 shows an exemplary balloon assembly with indentation 1210, tube connection point 508, distal edge 510, and inflation connection point 512. In some cases, aspects of indentation 1210 may resemble sleeves 504 as discussed above with regard to FIGs. 5, such that when the balloon 118 is

assembled, indentation 1210 is positioned thereon. Additionally, the balloon assembly 1300 may be assembled to create balloon 118 in a manner similar to that described with regard to FIG. 5.

[00130] FIGs. 14A-14E illustrate various exemplary configurations for the suction line 120. In some instances, the suction line 120 may be made from a rigid and/or flexible material and may be a one-piece or multi-piece construction. The suction line 120 may be configured into any appropriate shape. In some instances, the suction line 120 may be pre-configured to have a particular shape and/or may assume a particular shape as a result of being positioned within an indentation, such as indentation 1210. For example, suction line 120 may be configured into a triangular-type shape as shown in FIGs. 14A or a curved serpentine-type shape as shown in FIG. 14B. In the embodiments of FIGs. 14A and 14B, the suction line 120 may be pre-molded to adopt the shape of indentation 1210. The suction lines 120 of FIGs. 14A and 14B may have any number of holes 1410 by which fluid and other material may be removed from a patient's trachea by negative pressure applied by the suction line 120 via holes 1410. Holes 1410 may be placed in the suction line 120 in a uniform, clustered, and/or random pattern as may be appropriate for a particular application.

[00131] In some embodiments, the suction line 120 may have a flattened planar-type component as shown in FIGs. 14C and 14D with holes 1410 arranged thereon. FIG. 14C shows a flattened planar component of the suction line 120 with holes 1410 arranged in a random pattern and FIG. 14D shows a flattened planar component of the suction line 120 with holes arranged along an edge of the flattened planar component. The flattened planar component of FIG. 14D may also include channels or grooves 1425, which may be configured and/or arranged so as to assist with direction of fluids and secretions to the holes 1410 for eventual suction away from the trachea by negative pressure applied to the fluids supplied by the suction line 120.

[00132] FIG. 14E depicts an exemplary suction line 120 configured in an exemplary triangular-type shape with a plurality of suction protrusions or suction ports 1430. It is important to note that suction protrusions/ports 1430 are not drawn to scale in FIG. 14E and may extend from suction tube 120 by, for example, a few micrometers

(e.g., 5 or 10 micrometers) to a few millimeters (e.g., 0.5 – 5 mm). Suction protrusions/ports 1430 may extend from the suction line 120 in order to, for example, facilitate the application of negative pressure to a contacted tissue, fluid, or other substance.

[00133] FIGs. 15A and 15B illustrate the tracheal tube system 1200 with a shaped suction line 120 positioned within indentation 1210. More specifically, FIG. 15A illustrates a side view of tracheal tube system 1200 with the shaped suction line 120 positioned within indentation 1210 and FIG. 12B illustrates a front view of tracheal tube system 1200 with the shaped suction line 120 positioned within indentation 1210.

[00134] For illustrative purposes, FIGs. 15A and 15B show the triangular-shaped shaped suction line 120 of FIG. 14A as being positioned within indentation 1210, however, it will be appreciated by those of skill in the art that indentation 1210 may be sized, shaped, and/or positioned to accommodate any number of shaped suction lines 120.

[00135] In some embodiments, the suction balloon 118 may not include a pre-fabricated indentation 1210 and, in these embodiments, the suction line 120 may be positioned on a surface of the balloon 118. On some occasions, in these embodiments, the suction line 120 may form indentation 1210 by, for example, pressing down on a portion of the inflated balloon 118 when the tracheal tube system 1200 or 100 is inserted into a trachea.

[00136] As described herein, positioning suction line 120 on a surface of balloon 118 may include embodiments wherein suction line 120 (or a portion thereof) is permanently affixed to balloon 118 via, for example, a chemical, pressure, and/or heat generated bond. In other embodiments, suction line 120 may be positioned on a surface of balloon 118 via a flexible bond created by, for example, a flexible glue and/or lubricant. Further, the suction line 120 may removably positioned on a surface of balloon 118 via a simple placement of suction line 120 on the surface of the balloon 118 (i.e., no bond, or only a friction bond, between the surface of the balloon 118 and the suction line 120). Additionally, the suction line 120 may be positioned and/or held within indentation 1210 via a retention apparatus like a continuous or intermittent sleeve

or clamp and/or one or more straps. In some instances, the sleeve(s), clamp(s) and/or strap(s) may be laid on top of a positioned suction line 120 so as to keep the suction line 120 in place. Additionally, in some circumstances, a portion of suction line 120 may be held in place by a tracheal wall in which the tracheal tube system 1200 is placed.

[00137] The suction line 120 may be positioned on the balloon 118 such that the holes 1410 therein are not in contact with a surface of the balloon 118. In this way, the holes 1410 may face outward (relative to the surface of the balloon 118) such that when inserted into a trachea, the holes 1410 are in contact, or are nearly in contact, with the tissue of the tracheal opening so as to facilitate evacuation of fluid or other substances from a patient's trachea by the application of negative pressure via the suction line 120.

[00138] FIGs. 16A and 16B illustrate a tip end of an exemplary ablative surgical tool 1610 and a cystoscopy surgical tool 1615 that carry an ablative tip 1620 and a cautery tip 1625, respectively, both of which have a suction line 120 affixed thereto. Ablative and cystoscopic surgical tools are known in the art as tools for performing surgical procedures that involve the burning of undesirable tissue (e.g., cancerous or cystic) with an ablative or cauterizing tip, such as ablative tip 1620 and cauterizing tip 1625, so as to remove the undesirable tissue from the body of a patient. An undesirable byproduct of the use of ablative and/or cauterizing surgical techniques is the production of smoke as well as tissue fragments and liquids (e.g., blood, puss, etc.) that visually obscure the surgical field. Traditional methods of removing these ablative/cautery byproducts involve removal of the ablative/cystoscopy surgical tool from the surgical cavity so that a suction device (typically a surgical suction cannula) can be inserted into the surgical cavity to remove the ablative/cautery byproducts.

[00139] However, ablative and cystoscopy surgical tools 1610 and 1615 have a suction line 120 affixed thereto so that ablative/cauterizing byproducts can be removed from the surgical cavity as they are generated by negative pressure applied via either holes 1410 and/or and an open, or partially open, end of suction line 120. Affixation of the suction line 120 to the ablative and cystoscopy surgical tools 1610 and 1615 may act to reduce the time to perform the surgery and trauma to tissues surrounding the surgical site caused by the repeated insertion and removal of the ablative or cystoscopy surgical

tools and suction devices into/out of the surgical cavity as would be necessary to traditionally perform ablative or cystoscopic surgery. Additionally, or alternatively, affixation of the suction line 120 to the ablative and cystoscopy surgical tools 1610 and 1615 may act to improve visibility when performing ablative and cystoscopy surgical procedures by continuously, or nearly continuously, removing smoke, ash, tissue fragments, and/or liquids from the surgical field.

[00140] It will be appreciated by those of skill in the art that many types of surgical tools (scalpels, endoscopes, micro-scissors, clamps, etc.) may benefit from having a suction line, like suction line 120 affixed thereto to assist with the removal of, for example, tissue, liquid, blood, and/or smoke from the surgical field thereby improving the degree of visibility in the surgical field when performing a surgical procedure.

[00141] FIG. 17 is a cross-section view of a patient with tracheal tube system 1200 positioned within his trachea 1720. It should be noted that FIG. 17 is not drawn to scale. In the embodiment of FIG. 17, an assembly of balloon 118, indentation 1210, and suction line 120 are positioned below the patient's vocal cords 1710. The assembly may be positioned so that suction line 120, or a portion thereof, is in contact with a posterior portion of the tracheal wall 1725 for the evacuation of fluids, excretions, etc. from the trachea that may otherwise gather or pool on the posterior wall of the trachea 1720 due to gravitational force applied thereto. In some instances, it may be preferable to position the tracheal tube system 1200 assembly so that an upper junction between balloon 118 and catheter 106 may be located below (e.g., 0.1cm – 1.5 cm) the vocal cords 1710. Preferably, the upper junction is located 0.5 cm below the vocal cords 1710.

[00142] Hence, tracheal tubes, tracheal tube systems, and surgical tools with and suction devices attached thereto have been herein described. The negative pressure, or suction, applied (continuously, periodically, or on an as needed basis) by various embodiments of the tracheal tubes described herein extract pooling liquid and secretions as well as pathogens and foreign matter, which may serve as a breeding ground for bacteria and viruses and a collection agent for aerosolized pathogens, from a patient's trachea while intubated with any of the tracheal tubes herein described. Extraction of the pooling liquid and secretions from the trachea may serve to decrease instances of VAP

and other diseases because they do not travel beyond the suction line 120 and into the lungs.

[00143] Additionally, use of the tracheal tubes disclosed herein may serve to decrease discomfort typically associated with being intubated with a traditional tracheal tube because the suction and negative pressure applied by the suction line 120 is dispersed across the multiplicity of holes along suction line 120 and is not focused on a single hole. As a result, the amount of suction/negative pressure applied to a particular tracheal location used to remove secretions and other liquids is relatively small when compared to the amount of suction/negative pressure applied to only one location in the trachea (as would be the case with a single suction hole). This is clinically significant because the force exerted on the tracheal tissue is dispersed over a larger surface area. Consequently, the force exerted on any one point of tracheal tissue is less and, in this way, trauma and discomfort that may be caused by the exertion of force on the tracheal tissue is reduced. This enables negative pressure or suction to be applied to the trachea for a longer period of time without causing damage to sensitive tracheal tissues and irritation and discomfort to the patient.

[00144] In addition, embodiments of the tracheal tubes described herein may be deployed within a trachea of a patient regardless of the orientation of the patient (e.g., supine, prone, or on a side). For example, for the tracheal tube embodiments 100, 200A, and 200B, the suction line 120 wraps around the entire circumference of the balloon 118 and, as such, can apply negative pressure or suction to the tracheal walls regardless of the orientation of an intubated patient or the orientation of the tracheal tube when positioned within the patient. Additionally, for the tracheal tube embodiments 1200, the indentation 1210 and suction line 120 wrap around a partial circumference of the balloon 118 (from 60^{o} to 270^{o}) and, depending on the size of the portion of the circumference of the balloon 118 covered by the indentation 1210 and suction line 120, the suction line 120 can apply negative pressure or suction to the tracheal walls of the patient to extract pooling liquid and other materials regardless of the orientation of an intubated patient or the orientation of the tracheal tube when positioned within the patient, with the possible exception of a patient who is oriented in the opposition direction as the tracheal tube 1200, in which case gravity would cause the liquid/other material to pool on a portion of

the tracheal wall not contacted by, or sufficiently close to, the suction line 120 (e.g., if a patient is lying prone and the indentation 1210 and suction line 120 are oriented toward the posterior side of the patient). However, the occurrence of this exception is clinically rare and, if it were to occur, the tracheal tube 1200 could be slightly rotated so as to be positioned to provide negative pressure to fluids and other materials that may pool on the anterior portion of the tracheal wall.

[00145] Furthermore, the suction line 120 of the tracheal tube embodiments disclosed herein may act to maintain a desired position for the tracheal tube once inserted into a patient by adhering to the tracheal wall and, thereby, preventing slipping of the tracheal tube along the trachea.

[00146] Each embodiment disclosed herein may be used or otherwise combined with any of the other embodiments disclosed. Any element of any embodiment may be used in any embodiment.

[00147] Although the invention has been described with reference to specific embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the true spirit and scope of the invention. In addition, modifications may be made without departing from the essential teachings of the invention.

CLAIMS

I claim:

1. A tracheal tube system comprising:

a first tube that is flexible and hollow and having a first open end and a second open end;

an inflatable balloon affixed to and circumferentially surrounding a portion of the first tube, the inflatable balloon being positioned between the first end and the second end of the first tube and including an indentation sized and positioned to accommodate a portion of a second tube positioned therein when the inflatable balloon is inflated; and

the second tube positioned within the indentation, the second tube being hollow and having a multiplicity of holes along a sidewall not in contact with the inflatable balloon, wherein the second tube is configured to be coupled to a suction device that creates a negative pressure in the second tube.

2. The tracheal tube system of claim 1, wherein the second tube is curved.

3. The tracheal tube system of claim 1, wherein the indentation extends partially around a circumference of the inflatable balloon.

4. The tracheal tube system of claim 1, wherein the first end of the first tube is configured to be coupled to an artificial ventilation device.

5. The tracheal tube system of claim 1, wherein a portion of the indentation is positioned on the inflatable balloon coincident with a junction between the inflatable balloon and the first tube, the junction being positioned between the first end of the tube and the balloon.

6. The tracheal tube system of claim 1, wherein when the tracheal tube system is placed in a trachea, the negative pressure created by the suction device acts to suck fluid from the trachea through the holes in the second tube, thereby evacuating the fluid from the trachea.

7. The tracheal tube system of claim 1, wherein the indentation and the second tube are positioned such that when the tracheal tube system is inserted into a trachea, the inflatable balloon is inflated, and negative pressure is applied to the second tube by the suction device, the second tube is positioned against a portion of a tracheal wall.

8. The tracheal tube system of claim 1, wherein the indentation and the second tube are positioned such that when the tracheal tube system is inserted into a trachea and negative pressure is applied to the second tube by the suction device, the second tube is positioned against a posterior portion of a tracheal wall.

9. The tracheal tube system of claim 1, wherein the second tube is affixed to the balloon within the indentation via at least one of a bond, a sleeve, a strap, and a clamp.

10. The tracheal tube system of claim 1, wherein the first tube has a lumen coupled to the suction device and negative pressure in the lumen causes negative pressure in the second tube.

11. The tracheal tube system of claim 1, wherein the second tube is flexible.

12. A tracheal tube system comprising:

a first tube that is flexible and hollow and having a first open end and a second open end;

an inflatable balloon affixed to and circumferentially surrounding a portion of the first tube, the inflatable balloon being positioned between the first end and the second end of the first tube; and

a second tube positioned on an exterior surface of the inflatable balloon, the second tube being hollow and having a multiplicity of holes along a sidewall not in contact with the inflatable balloon, wherein the second tube is configured to be coupled to a suction device that creates a negative pressure in the second tube.

13. The tracheal tube system of claim 12, wherein the second tube is curved.

14. The tracheal tube system of claim 12, wherein the second tube extends partially around a circumference of the inflatable balloon.

15. The tracheal tube system of claim 12, wherein the first end of the first tube is configured to be coupled to an artificial ventilation device.

16. The tracheal tube system of claim 12, wherein a portion of the second tube is positioned on the inflatable balloon coincident with a junction between the inflatable balloon and the first tube, the junction being positioned between the first end of the tube and the balloon.

17. The tracheal tube system of claim 12, wherein when the tracheal tube system is placed in a trachea, the negative pressure created by the suction device acts to suck fluid from the trachea through the holes in the second tube, thereby evacuating the fluid from the trachea.

18. The tracheal tube system of claim 12, wherein the second tube is positioned on the inflatable balloon such that when the tracheal tube system is inserted into a trachea, the inflatable balloon is inflated, and negative pressure is applied to the second tube by the suction device, the second tube is positioned against a portion of a tracheal wall.

19. The tracheal tube system of claim 12, wherein the second tube is positioned such that when the tracheal tube system is inserted into a trachea and negative pressure is applied to the second tube by the suction device, the second tube is positioned against a portion of a posterior tracheal wall.

20. The tracheal tube system of claim 12, wherein the first tube has a lumen coupled to the suction device and negative pressure in the lumen causes negative pressure in the second tube.

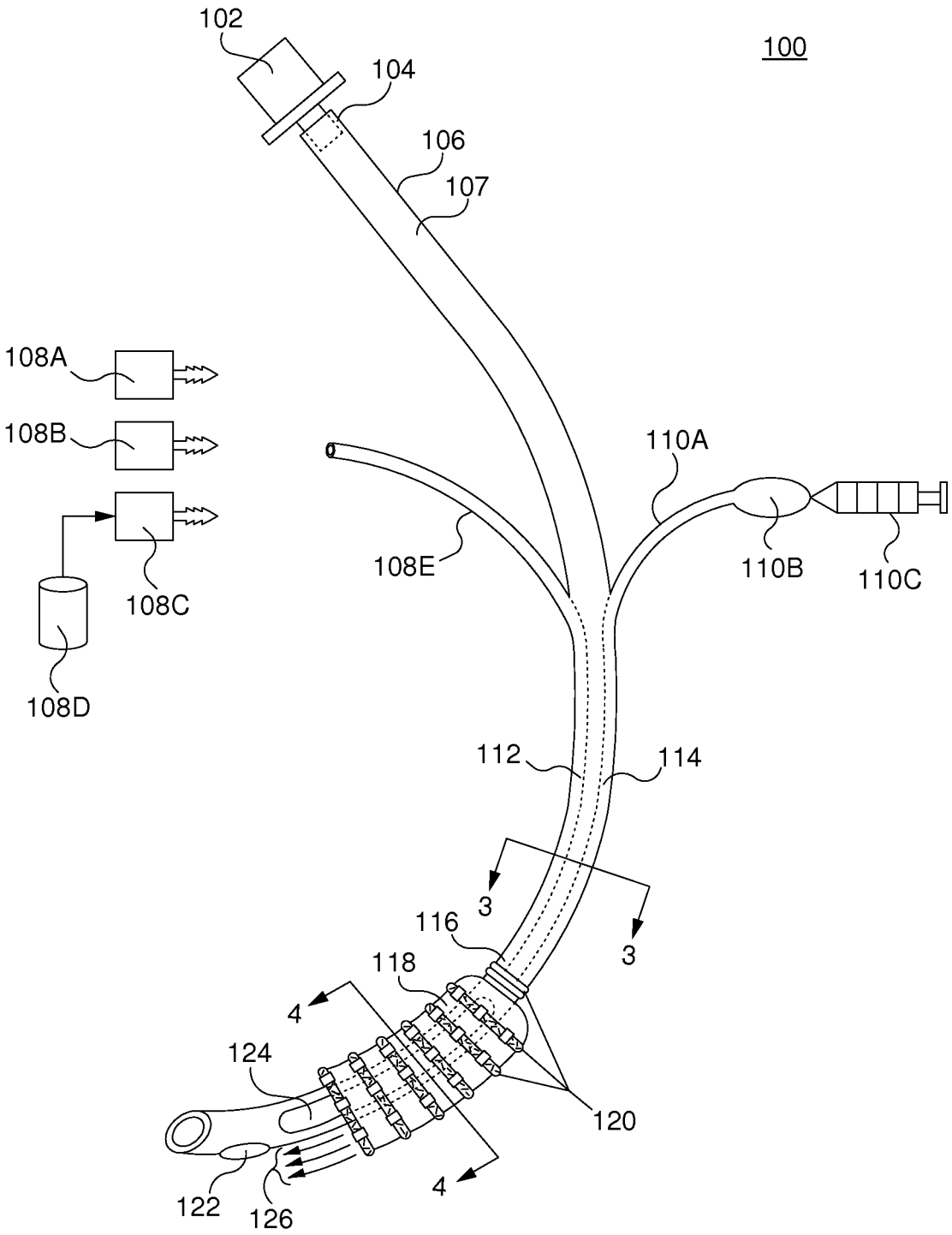

102
100
104
106
107
108A
108B
108C
108D
108E
110A
110B
110C
112
114
3
3
116
118
4
4
120
122
124
126

Figure 1

200A

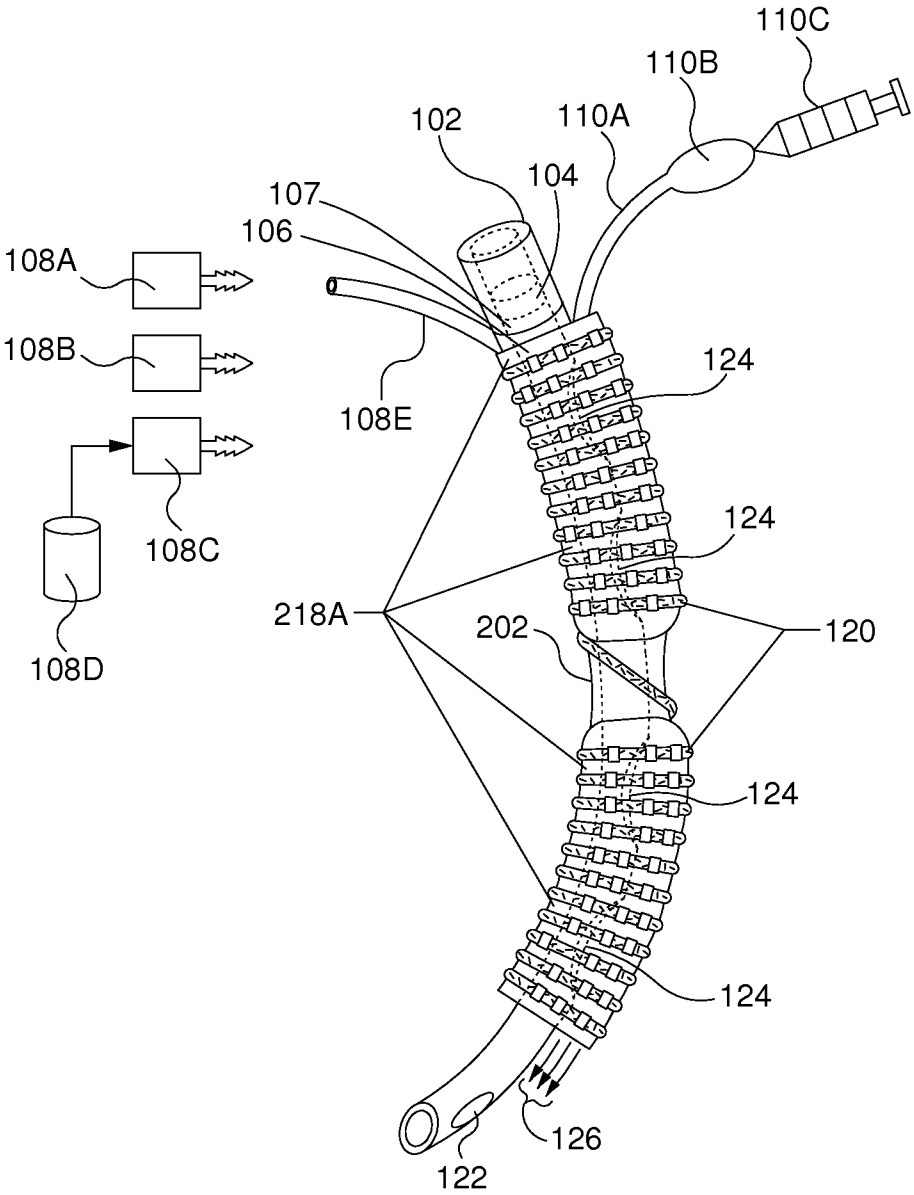


Figure 2A

200B

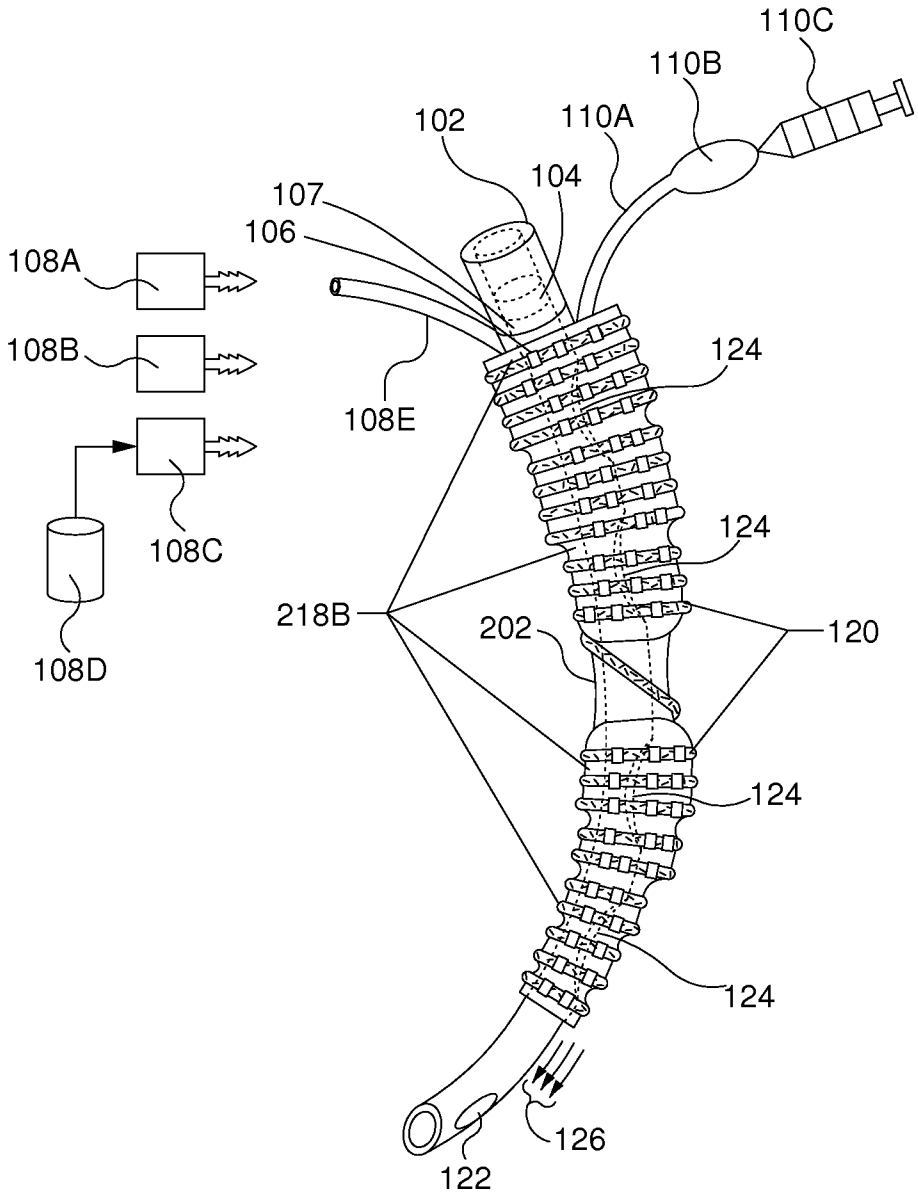


Figure 2B

300

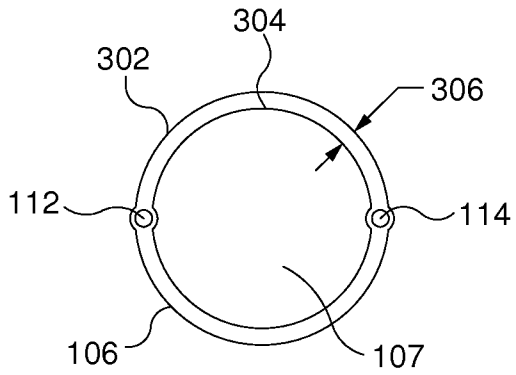


Figure 3

400

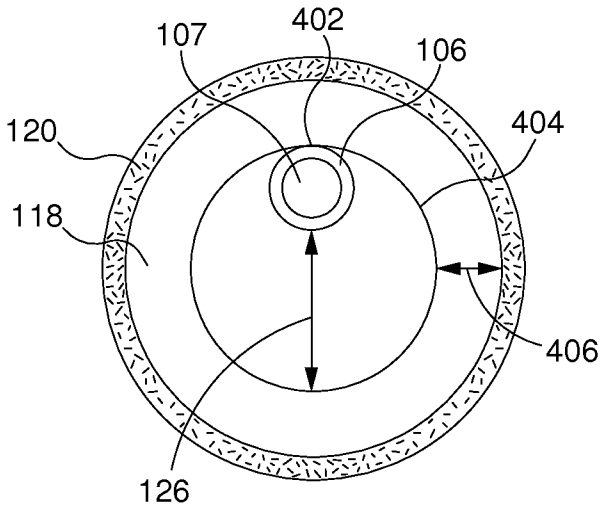


Figure 4

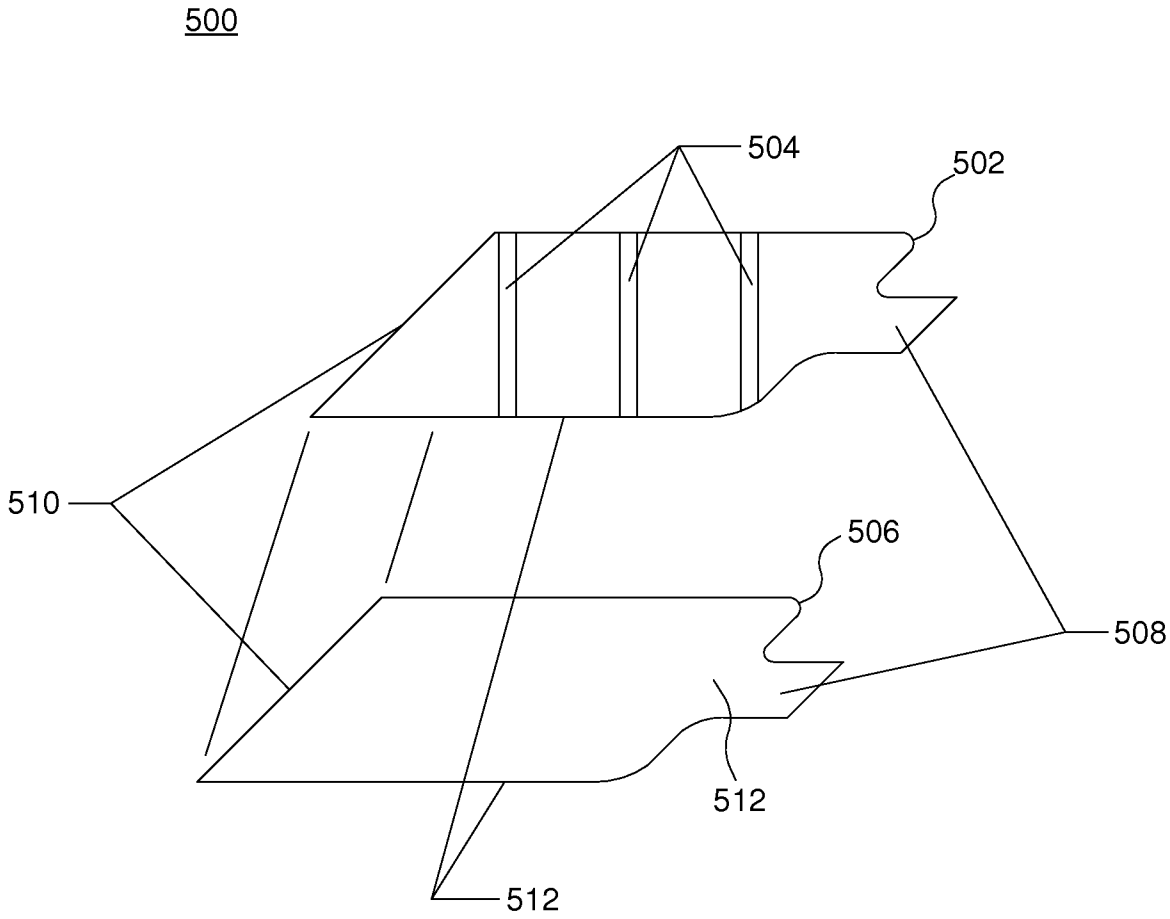


Figure 5

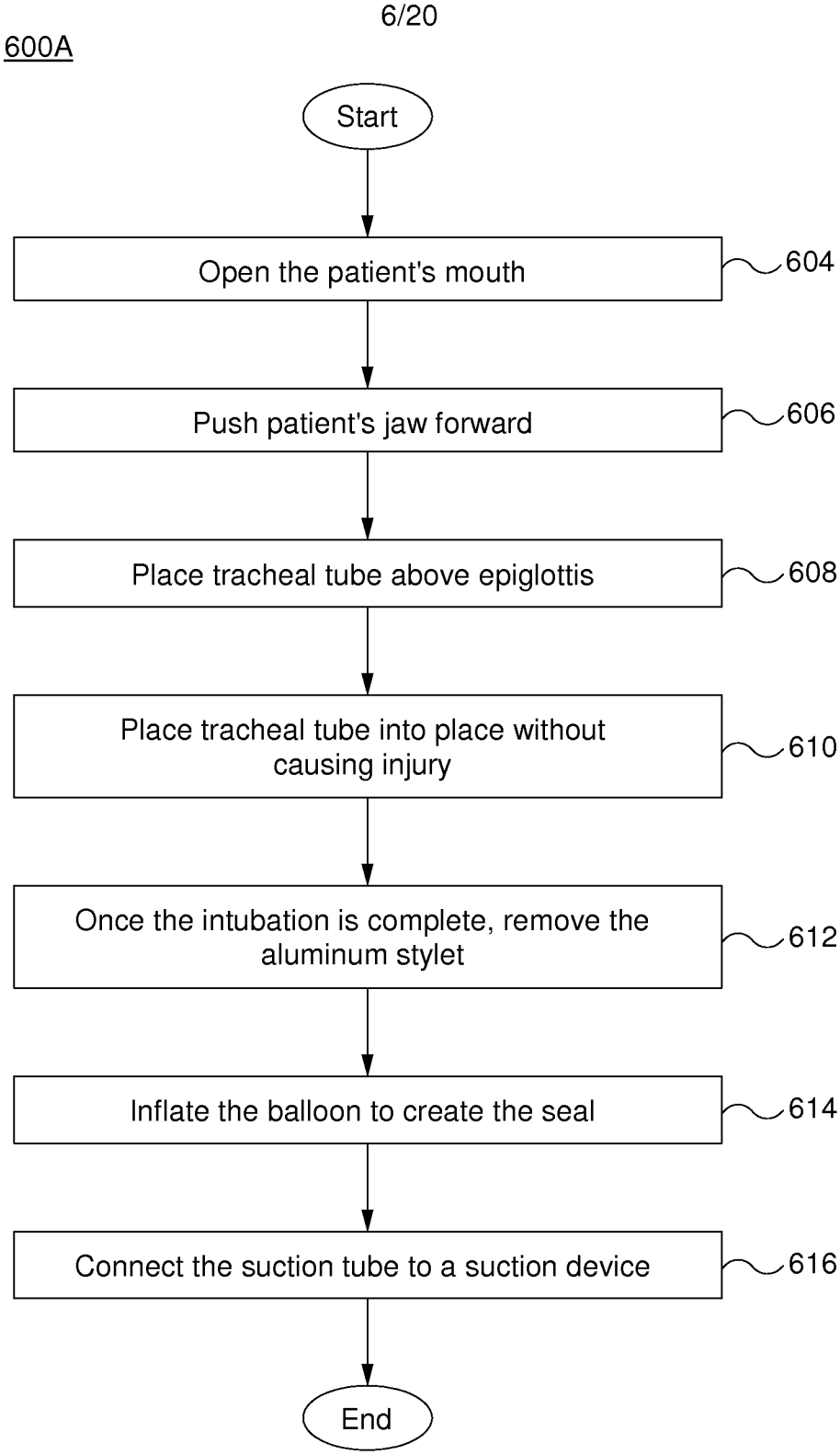

600A
Start
Open the patient's mouth
604
Push patient's jaw forward
606
Place tracheal tube above epiglottis
608
Place tracheal tube into place without causing injury
610
Once the intubation is complete, remove the aluminum stylet
612
Inflate the balloon to create the seal
614
Connect the suction tube to a suction device
616
End

Figure 6A

600B

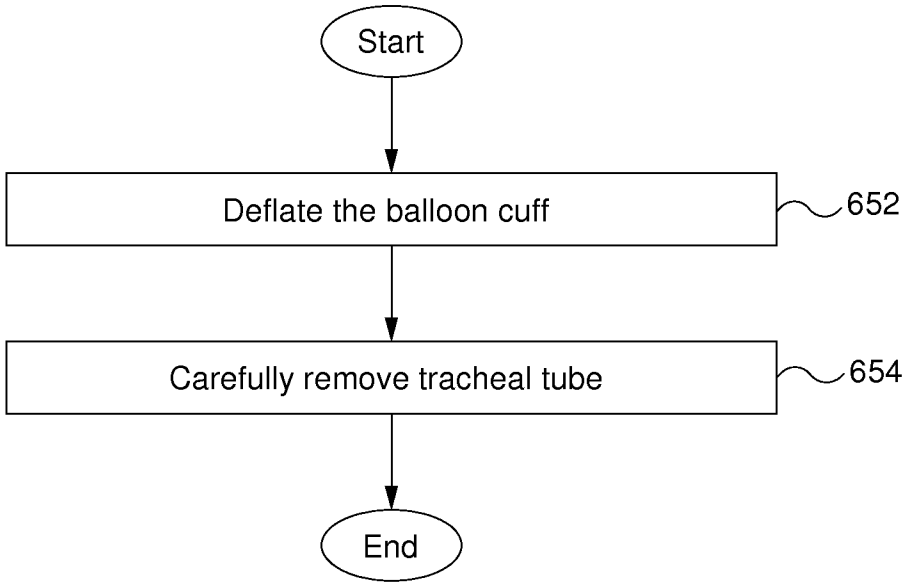


Figure 6B

700A

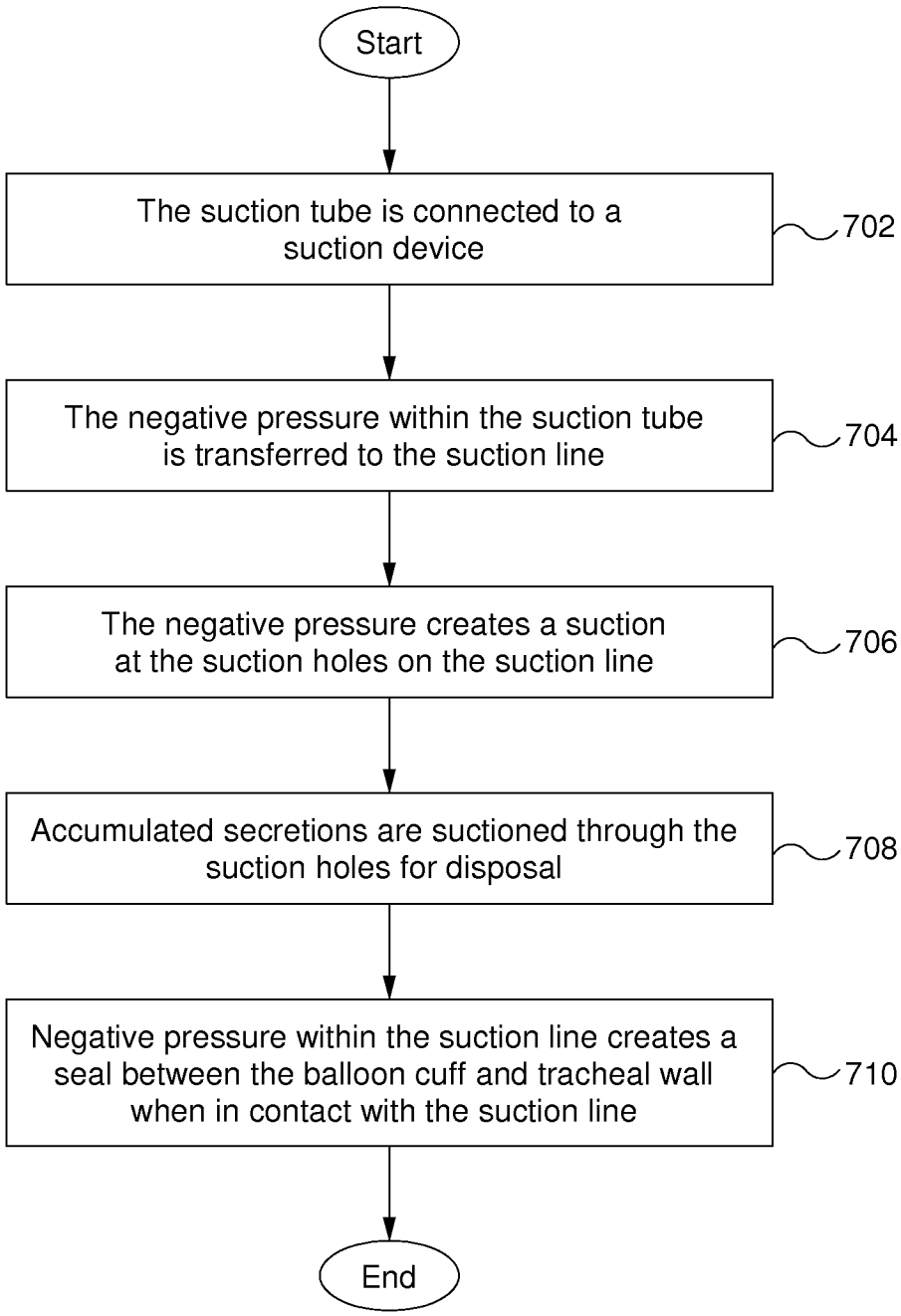


Figure 7A

700B

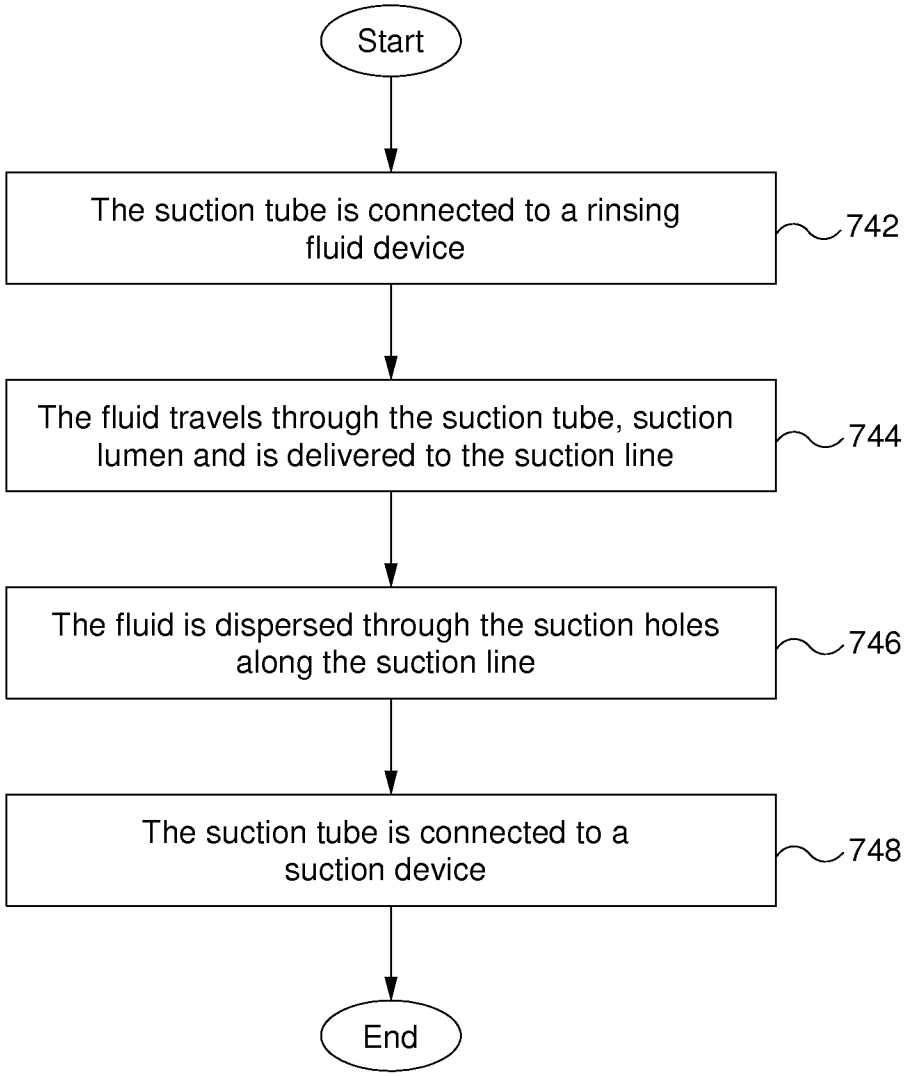


Figure 7B

700C

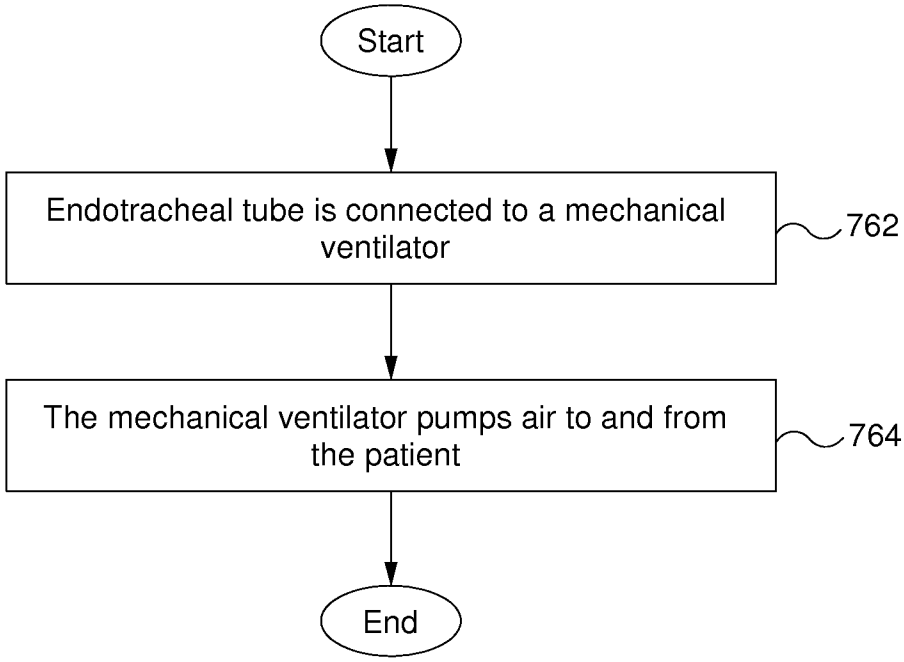


Figure 7C

800

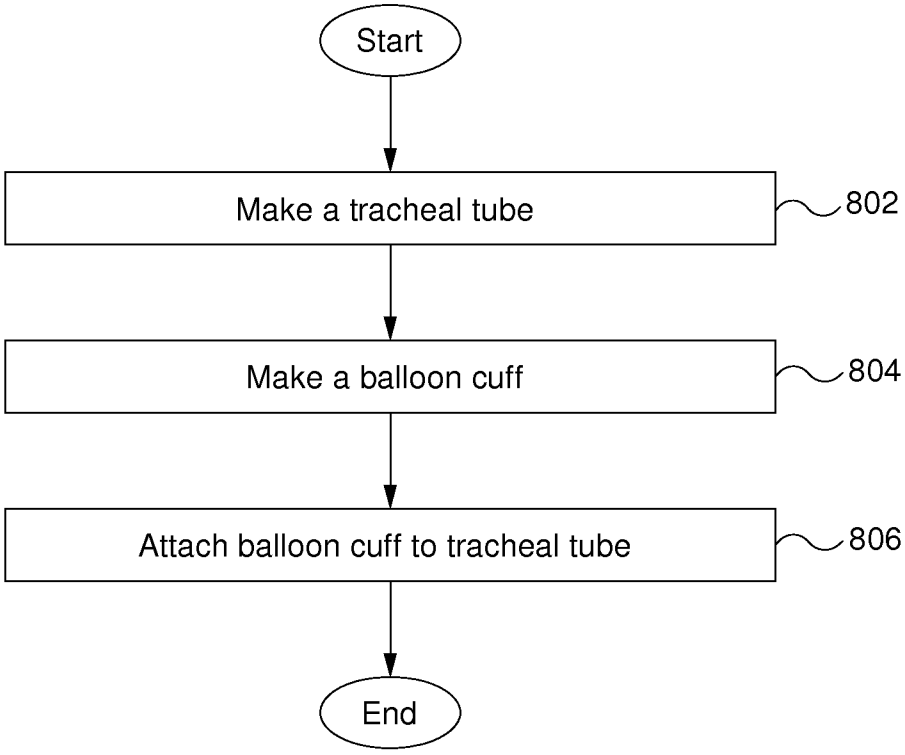

Start
Make a tracheal tube
802
Make a balloon cuff
804
Attach balloon cuff to tracheal tube
806
End

Figure 8

802

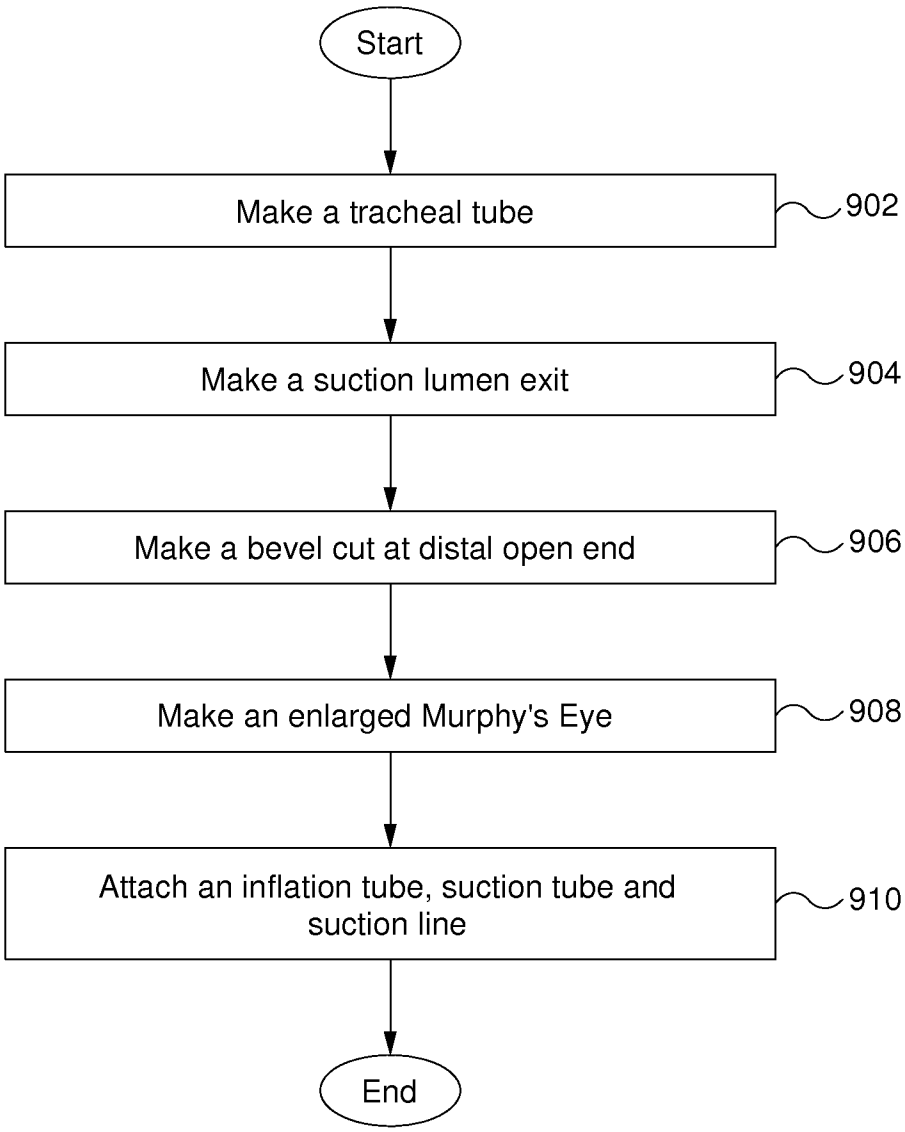

Start
Make a tracheal tube
902
Make a suction lumen exit
904
Make a bevel cut at distal open end
906
Make an enlarged Murphy's Eye
908
Attach an inflation tube, suction tube and suction line
910
End

Figure 9

804

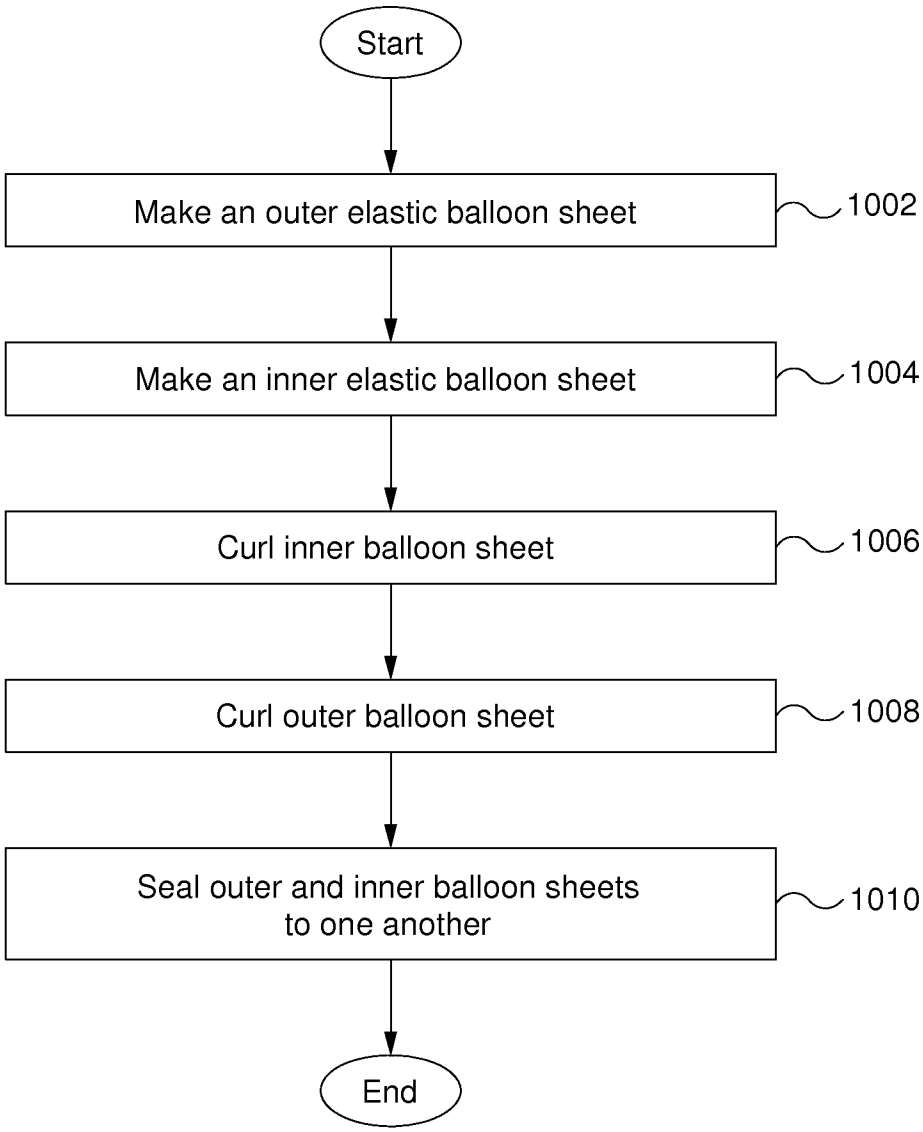


Figure 10

806

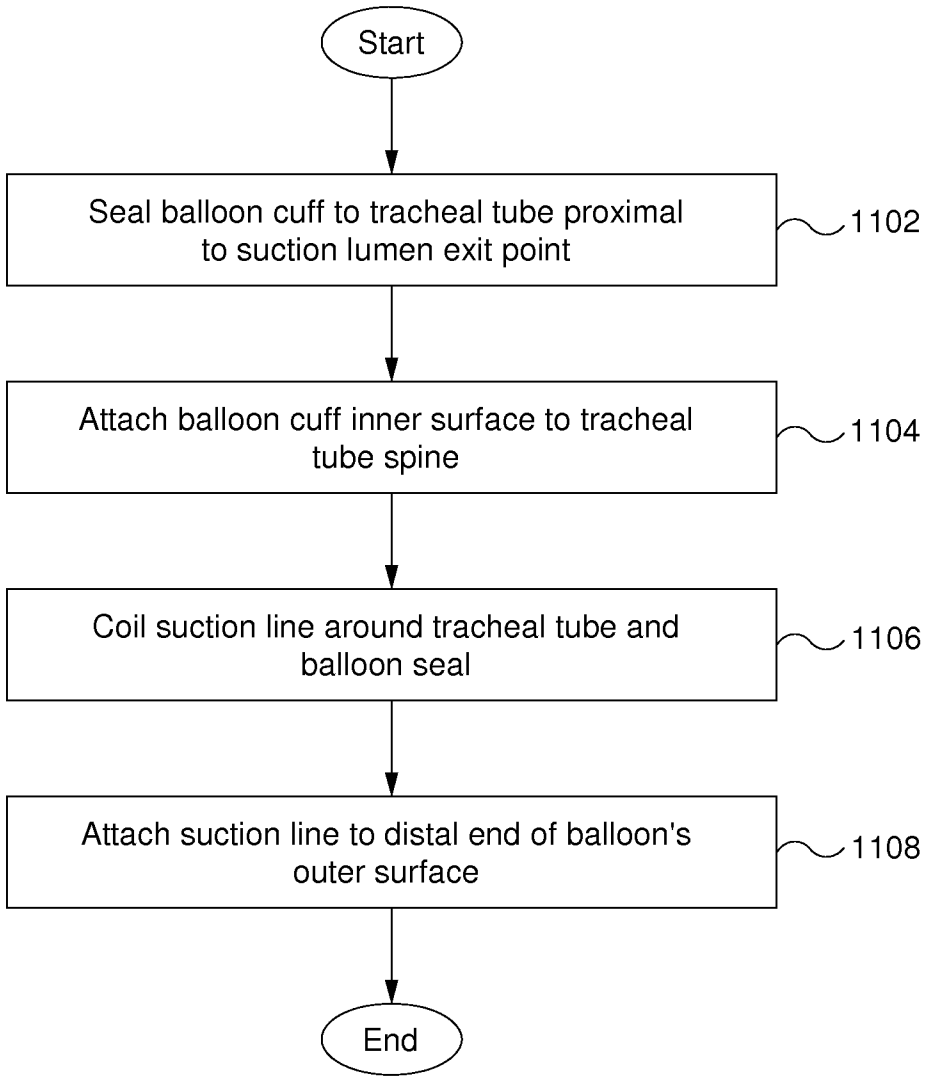


Figure 11

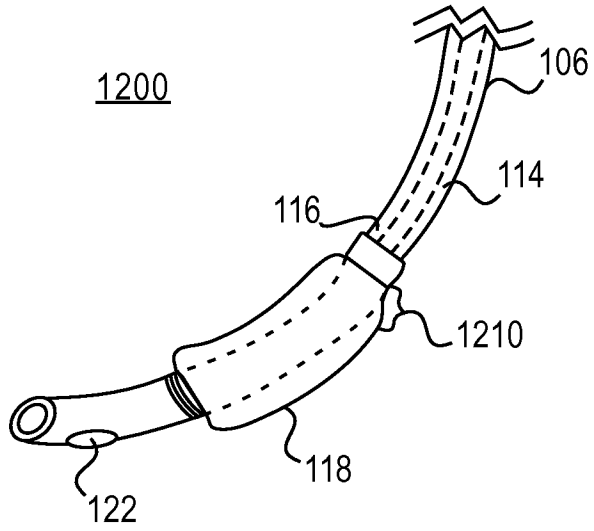


FIG. 12A

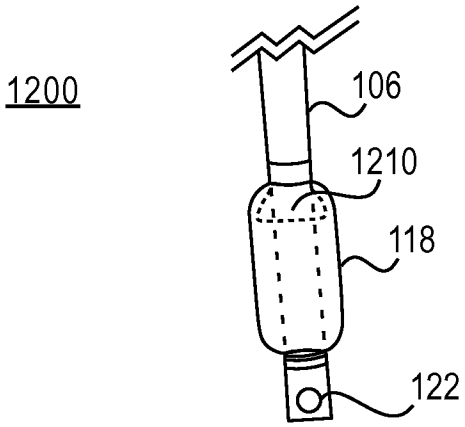


FIG. 12B

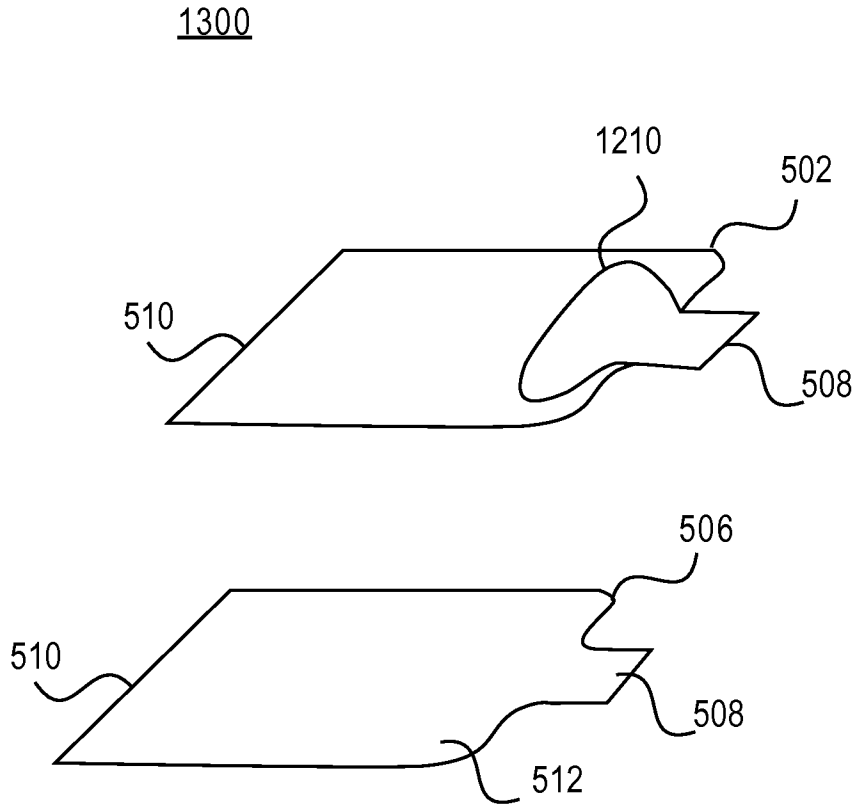


FIG. 13

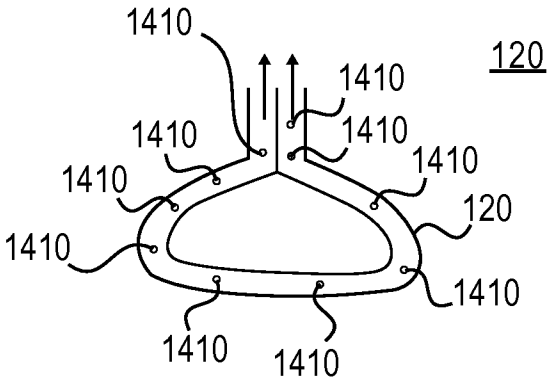


FIG. 14A

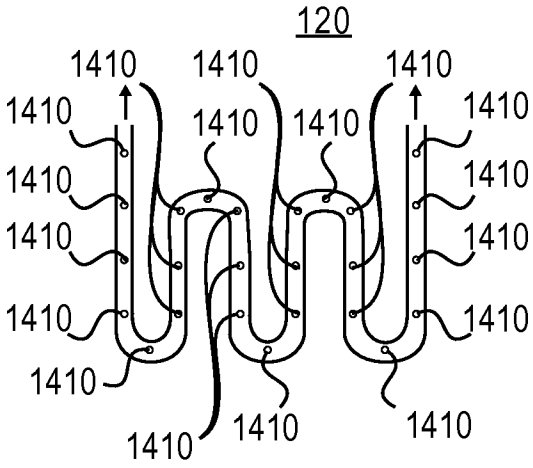


FIG. 14B

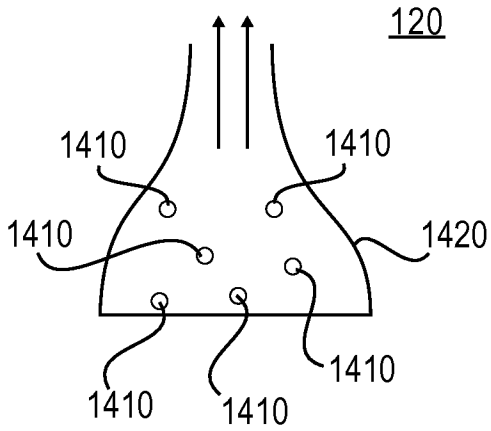


FIG. 14C

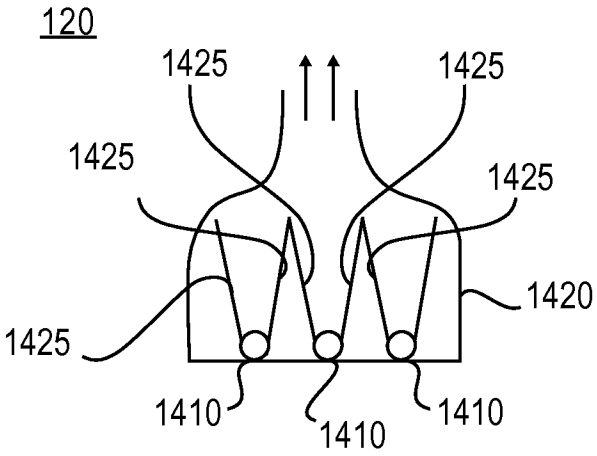


FIG. 14D

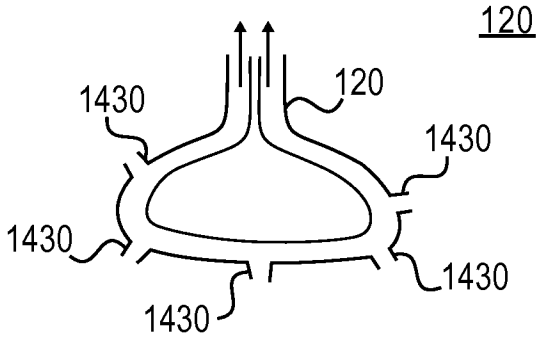


FIG. 14E

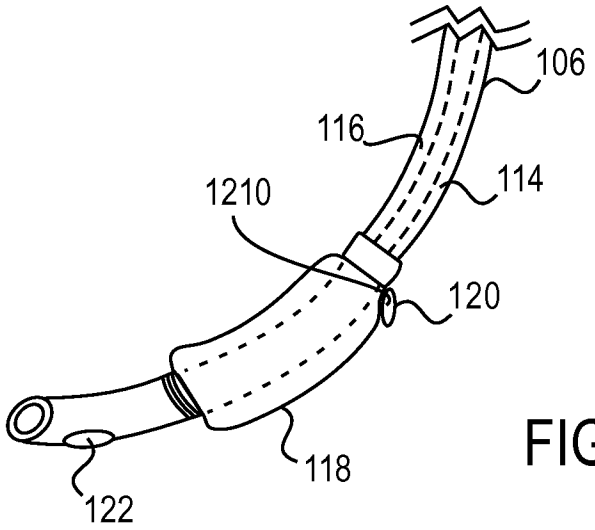


FIG. 15A

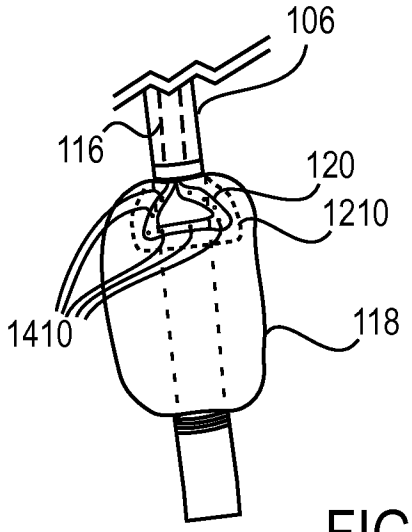


FIG. 15B

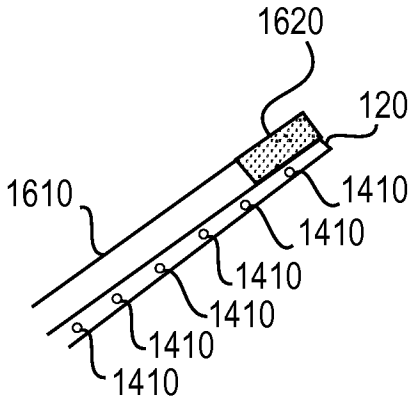


FIG. 16A

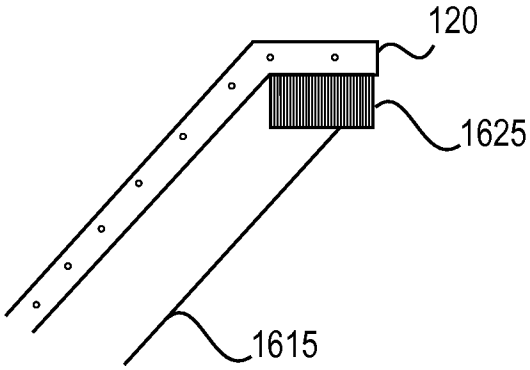


FIG. 16B

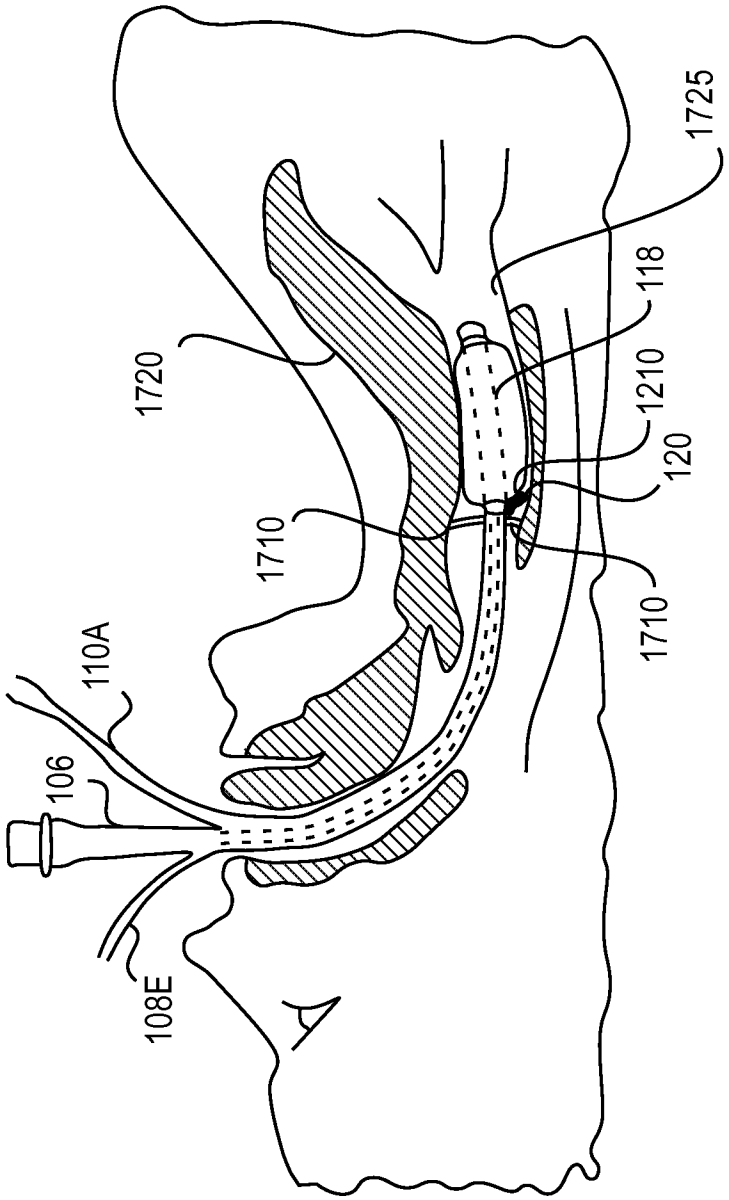


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/059958

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/04(2006.01)i, A61M 29/02(2006.01)i, A61M 1/00(2006.01)i

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 16/04; B23P 17/04; A61M 16/00; A61B 5/00; A61M 29/02; A61M 1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: tracheal tube, balloon, inflation, suction, hole, indentation

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004-0255951 A1 (GREY, C.) 23 December 2004 See abstract; figures 1-11; paragraphs [0048]-[0049]; claims 1-5.	1-11
A		12-20
Y	US 2009-0260632 A1 (ABNOUSI, F. et al.) 22 October 2009 See abstract; figures 1-5E; paragraph [0031]; claims 1-20.	1-11
A		12-20
A	WO 2012-087837 A1 (C. R. BARD, INC.) 28 June 2012 See abstract; figures 1-8; claims 1-25.	1-20
A	US 2011-0139159 A1 (NELSON, D. S. et al.) 16 June 2011 See abstract; claims 1-10.	1-20
A	US 5715816 A (MAINIERO, L. M. et. al) 10 February 1998 See abstract; claims 1-5.	1-20

☐ 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
28 January 2015 (28.01.2015)	**28 January 2015 (28.01.2015)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2014/059958

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 2004-071553 A2	26/08/2004
		WO 2004-071553 A3	23/02/2006
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WO 2012-087837 A1	28/06/2012	None	
US 2011-0139159 A1	16/06/2011	US 2008-0110468 A1	15/05/2008
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		EP 0979054 A1	16/02/2000
		US 05417207 A	23/05/1995
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		US 6322518 B1	27/11/2001
		US 6438400 B1	20/08/2002