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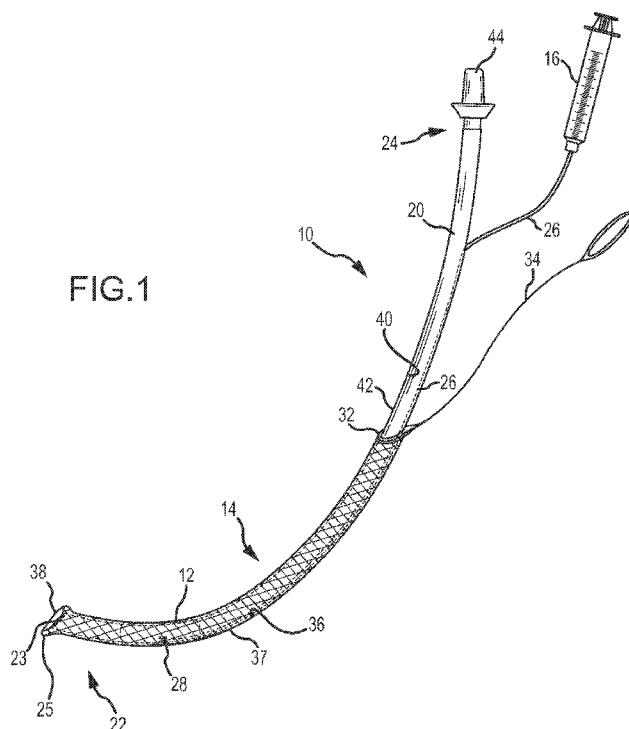
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(54) Title: TRACHEAL TUBE SHEATH



(57) Abstract: A sheath for protecting an endotracheal tube assembly before and during intubating a patient. The sheath includes a proximal end and a distal end, an inner diameter forming an inner elongated portion, an outer diameter forming an outer elongated portion, and a distal deformed, tapered, and/or textured portion. The endotracheal tube is positioned adjacent to the inner elongated portion of the sheath, before and during intubation of a patient.



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TRACHEAL TUBE SHEATH

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to United States Provisional Patent Application Serial Number 61/858,328, filed July 25, 2013, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present disclosure relates to medical devices. More particularly, the disclosure relates to protective sheaths for tracheal tube devices such as endotracheal tubes.

BACKGROUND OF THE INVENTION

[0003] This section is intended to introduce the reader to various aspects of art that may be related to aspects of the present invention which are described and/or claimed below. This section is believed to be helpful in providing the reader with background information to help understand the various aspects of the present invention. Accordingly, it should be understood that the statements in this section are to be read in this light, and not as admissions of prior art.

[0004] Tracheal intubation is an established procedure for controlling the airway of patients undergoing certain types of medical procedures. Conventional methods of tracheal intubation include the insertion of a tubular device, such as an endotracheal tube, through the patient's mouth and into the patient's trachea. The distal end of the endotracheal tube is then positioned above the patient's carina to allow air to pass through the tube and into the lungs. The tube is often coupled to an air source, such as a ventilator, to mechanically assist with oxygenation and ventilation of the lungs. To properly position the endotracheal tube, the medical professional may use various devices to improve their line of sight, such as, for example, laryngoscopes, flexible fiberoptic bronchoscopes, or video laryngoscopes.

[0005] In order to create the necessary air pressure to mechanically oxygenate and ventilate the lungs, the gaps between the outer walls of the endotracheal tube and trachea should be sufficiently sealed. Sealing the passageway may be accomplished by using an inflatable cuff provided around the endotracheal tube near the distal end of the tube. Before sealing the passageway, the cuff is generally positioned within the trachea, below the vocal cords, and above the carina. Once inflated, the cuff may also act as an anchor below the vocal cords to help prevent displacement of the tube.

[0006] Although this method of treatment has been successful, problems remain. For example, a common problem with using tracheal tube devices is that during or prior to placement of the tube, the distal end of the tube may be contaminated with flora, mucus, saliva, blood, vomit, and other contaminants from the patient's mouth or oropharynx, and/or the surrounding environment. During intubation, the contaminated distal end of the tube may push the contaminants into the trachea or a main stem bronchus, potentially causing infections such as ventilator associated pneumonia leading to increased morbidity and mortality—markedly increasing the cost of care for these patients.

[0007] The art of the present invention differs substantially from the art of stents in the area of delivery, strength, dimensions, function, components, corresponding supporting surgical devices, wall construction, and removability.

BRIEF SUMMARY OF THE INVENTION

[0008] The disclosure is directed to several alternative designs, materials, and methods of manufacturing protective sheaths for tracheal tube devices such as endotracheal tubes. It shall not limit the invention in any respect. A detailed and fully enabling disclosure is set forth in the detailed description section.

[0009] One embodiment of the present invention may include a sheath for protecting an endotracheal tube assembly during intubation of a patient. The sheath may be sized and

configured to substantially house an endotracheal tube having a curve along its length from a proximal end to a distal end. The sheath may be advantageously configured to protect the distal half and distal end of the endotracheal tube from contaminants during and prior to intubation, such as, for example flora, mucus, saliva, blood, vomit, and other contaminants from the patient's mouth or oropharynx, and/or the surrounding environment. If left unprotected the distal end of the tube may deliver such contaminants into the trachea or a main stem bronchus, potentially causing infections such as ventilator associated pneumonia leading to increased morbidity and mortality.

[0010] In some embodiments, the sheath may include distal and proximal ends, an inner diameter forming an elongated inner portion and an outer diameter forming an elongated outer portion. The elongated inner portion being substantially adjacent to the endotracheal tube. The cross-sectional shape of the elongated inner and outer portion may have a generally tubular or cylindrical flexible structure that is configured to conform around the endotracheal tube. The cross-sectional shape of the elongated inner and outer portion may alternatively be substantially ellipsoidal, rectangular, hexagonal, rectangular, square, or polygonal in shape. The distal end of the sheath may substantially cover the distal end of the endotracheal tube. In some embodiments, the sheath may include a substantially small slit that opens as the distal end of the tube slides through the sheath.

[0011] The sheath may include a deformed, tapered, and/or textured portion towards the distal end of the sheath. The deformed, tapered, and/or textured portion may be sized and configured to provide resistance against the patient's vocal cords or supraglottic structures near the vocal cords before the distal end of the endotracheal tube enters the trachea. The vocal cords or surrounding supraglottic structures restrict the deformed or tapered portion of the sheath by applying a force against the sheath in the longitudinal direction parallel to the endotracheal tube. As force is applied, the distal end of the endotracheal tube is allowed to

slide through the sheath and into the trachea while the distal end of the sheath remains proximal to the vocal cords.

[0012] In some embodiments, the tapered portion is sized and configured to substantially cover the distal end of the endotracheal tube while still allowing for an air/oxygen mixture or anesthetic gas to flow through the endotracheal tube. The degree of taper, curvature and/or linearity at different parts of the sheath may vary. For example, the distal end of the sheath may be tapered differently or opposite, or may be generally symmetrical, without substantial taper from one end to the other. Likewise, other sheath shapes having straight walls, curved walls, or combinations of straight and curved walls are possible and are within the scope of the present disclosure.

[0013] The sheath may be formed from materials having suitable mechanical properties resistant to punctures, tears, pin holes, and chemical properties to provide for flexibility, as well as biocompatibility. The materials may include polyurethane or polyurethane-based compositions having suitable mechanical and chemical properties. Other materials may be suitable that exhibit properties enabling them to be processed into a protective sheath.

[0014] In some embodiments, it may be desirable to form the sheath from an antimicrobial material or for the sheath to include a microbial control layer. The sheath or microbial control layer may be formed from hydrophobic polymers including a hydrophilic polymer or other antimicrobial materials. The sheath material or microbial control layer may comprise a metal, such as gold, copper, or silver that exhibits antimicrobial properties. In addition, the sheath material or microbial control layer may include an acrylamide polymerization solution (i.e., polyacrylamide solution) that may be polymerized and crosslinked by thermal initiation such as ultraviolet radiation. The pore size of the solution may be controlled by altering the amount of crosslinking and the percent of solids in the

monomer solution. The microbial control layer may be applied to the sheath by dipping the sheath into a polyacrylamide solution. The thickness of the microbial control layer may be altered by varying the number of times or duration that the sheath is dipped into the polyacrylamide solution. The microbial control layer may be applied to both the elongated inner and outer portion of the sheath. The microbial control layer may also be extruded, molded, co-extruded, blow-molded, electrostatically applied, or sprayed onto the sheath.

[0015] In some embodiments the sheath or microbial control layer may have reflective or radiopaque properties. For example, the sheath or microbial control layer may comprise antimicrobial metal having sufficient reflective properties. Accordingly, in some embodiments, a medical professional may be able to detect the sheath or portions of the sheath by ultrasonography or by other detection devices.

[0016] The sheath may include a tether attached to the proximal end of the sheath and extending towards the proximal end of the endotracheal tube. The length of the tether may vary depending on the length of the sheath. The tether may help a medical professional slide the sheath to a position proximal to the patient's mouth during or after intubation. Under certain circumstances it may be important for a medical professional to have a free hand to operate various devices, such as, for example, a laryngoscope. Accordingly, in one embodiment, the sheath is sized and configured to allow a medical professional to slide the sheath with one hand while intubating a patient—thereby freeing the other hand. In one embodiment, the tether may be sized and configured to allow a medical professional to slide the sheath with one hand by using a thumb. The sheath may be removed or secured into position in the proximal position to the patient's mouth. The sheath is void of exterior tear-away perforations that may collect or harbor microbes.

[0017] The sheath may be sized and configured to house various sizes of endotracheal tubes including a number of feature refinements and additional features applicable to the

endotracheal tube. For example, the endotracheal tube may include a cuff operatively associated with at least one pilot balloon or syringe assembly for deflating and inflating the cuff. The pilot balloon assembly may include a pilot balloon pump in the form of a syringe and at least one conduit having a distal end terminating within the cuff and a proximal end that may be coupled to a syringe. The conduit may be positioned along the inner portion of the endotracheal tube for delivering or extracting a fluid, such as air, to or from the rolling cuff.

[0018] Another embodiment is a method for manufacturing the sheath. The size and shape of the sheath may be formed by various methods. For example, injection molding, blow molding, stretch molding, extrusion, dip molding, casting, or any other suitable technique. In some embodiments, the sheath may be manufactured to include a slight taper, being wider at the distal end, as discussed above. The sheath may also be simultaneously formed with the tether. Alternatively, the tether may be attached to the sheath after the main body, including the elongated inner and outer portion of the sheath, is formed. The tether may be attached to the main body adhesively, fixed or coupled with solvent bonding, vibration welding, induction welding, mechanical fastening, or by any other biocompatible means that would provide for a sufficient attachment method.

[0019] The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

[0021] FIG. 1 is a perspective view of an exemplary protective sheath housing an endotracheal tube assembly in accordance with one embodiment of the invention;

[0022] FIG. 2 is a perspective view of the sheath transitioning towards the proximal end of the endotracheal tube;

[0023] FIG. 2A is a perspective view of the sheath continuing to transfer towards the proximal end of the endotracheal tube;

[0024] FIG. 2B is a perspective view of the sheath compressed near the proximal end of the endotracheal tube;

[0025] FIG. 3 is a perspective view of the distal end of the sheath having a deformed or tapered section substantially covering the distal end of the endotracheal tube;

[0026] FIG. 4 is a partial plain view of an exemplary protective sheath and endotracheal tube assembly before having the distal end of the endotracheal tube pass through the vocal cords of a patient;

[0027] FIG. 5 is a partial plain view of an exemplary protective sheath and endotracheal tube assembly after the distal end of the endotracheal tube passes through the vocal cords of the patient;

[0028] FIG. 6 is a partial plain view of an exemplary protective sheath and endotracheal tube assembly after the distal end of the endotracheal tube is positioned within the trachea and the protective sheath is retracted to a position proximal to the mouth of the patient;

[0029] FIG. 7 is a coronal cross-sectional view of FIG. 4 illustrating the protective sheath and endotracheal tube assembly before having the distal end of the endotracheal tube pass through the vocal cords of the patient;

[0030] FIG. 8 is a coronal cross-sectional view of FIG. 5 illustrating the protective sheath and endotracheal tube assembly after the distal end of the endotracheal tube passes through the vocal cords of the patient; and

[0031] FIG. 9 is a coronal cross-sectional view of FIG. 6 illustrating the protective sheath and endotracheal tube assembly after the distal end of the endotracheal tube is positioned within the trachea and the protective sheath is in the process of being retracted to a proximal position.

[0032] While the invention is susceptible to various modifications and alternative forms, specifics of the invention have been shown by way of example in the drawings and will be described in further detail below. It should be understood that the intention of the detailed description does not limit aspects of the invention to the particular embodiments described. On the contrary, the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0033] The following defined terms disclosed in this detailed description of the invention shall apply to the invention, unless a different definition is given in the claims or elsewhere in this specification.

[0034] All numeric values are assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about” generally refers to a range of numbers that a person having ordinary skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In addition, in many instances, the term “about” may be indicative as including numbers rounded to the nearest significant figure. The recitation of numerical ranges by endpoints includes all numbers within that range. Although some suitable dimensions, ranges, and/or values pertaining to various components, features and/or specifications are disclosed, a person having ordinary skill in the art, incited by the present disclosure, would understand that the desired dimensions, ranges and/or values may deviate from those expressly disclosed.

[0035] As used in this specification and the appended claims, the singular forms “a” “an” and “the” include the plural referents unless the content clearly dictates otherwise. As used in this specification and the claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

[0036] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into additional embodiments unless clearly stated to the contrary. While the embodiments herein may be described in terms of spatial orientation, the terminology used is not intended to be limiting, but instead to provide a straightforward description of the various embodiments.

[0037] Primarily referring now to FIGs. 1-4 and 7, which show components of an exemplary sheath 14 for protecting endotracheal tube assembly 10 during intubation in accordance with one example embodiment. Sheath 14 may comprise a distal end 38 and proximal end 32, a tapered portion 25, an inner diameter forming an elongated inner portion 36 and an outer diameter forming an elongated outer portion 37, as well as tether 34. Endotracheal tube assembly 10 may comprise a distal end 22 and proximal end 24, cuff 12, tube 20 having inner portion 40 and outer portion 42, beveled portion 23, adapter 44, syringe 16, conduit 26, and port 28.

[0038] Sheath 14 may be sized and configured to protect the distal half and distal end 22 of endotracheal tube 20 from contaminants during and prior to intubation, including, for example—flora, mucus, saliva, blood, vomit, and other contaminants from the mouth 74 or oropharynx of a patient 78, and/or the surrounding environment. Microbial contaminants

may include, for example, *Streptococcus*, *Candida albicans* (yeast), *phomonas multiphilia*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterobacter* spp, and *Haemophilus influenza*. If left unprotected, a portion of tube 20 including distal end 22 and cuff 12 may deliver contaminants into the trachea 66 or a main stem bronchus 84, potentially causing infections such as ventilator associated pneumonia leading to increased morbidity and mortality.

[0039] In order to protect the distal end 22 of tube 20, the elongated inner portion 36 of sheath 14 is positioned substantially adjacent to tube 20. Sheath 14 may be sized and configured to protect the portion of tube 20 that enters the trachea 66, including an inflatable cuff 12. Sheath 14 may comprise a flexible material that conforms to a slight curve along the length of tube 20 and over cuff 12. Sheath 14 may extend along tube 20 to cover the distal half of tube 20. In some embodiments, sheath 14 may be advantageously sized and configured to allow a medical professional or technician to retract and anchor sheath 14 to tube 20 in a position proximal to the mouth 74 of patient 78 during or after intubation. The cross-sectional shape of the elongated inner portion 36 and outer portion 37 of sheath 14 may have a generally tubular or cylindrical flexible structure that is configured to help conform around the endotracheal tube 20 and cuff 12. The cross-sectional shape of the elongated inner portion 36 and outer portion 37 may alternatively be substantially ellipsoidal, rectangular, hexagonal, rectangular, square, or polygonal in shape.

[0040] Prior to intubation, sheath 14 may be positioned adjacent to tube 20 by a medical professional or technician by sliding distal end 22 of tube 20 through proximal end 32 of sheath 14. The size and shape of sheath 14 may be formed by various methods. For example, injection molding, blow molding, stretch molding, extrusion, dip molding, casting, or any other suitable technique. Sheath 14 may also be simultaneously formed with tether 34. Alternatively, tether 34 may be attached to the proximal end 32 of sheath 14 after sheath 14 is

formed. Tether 34 may be attached to sheath 14 adhesively, fixed or coupled with solvent bonding, vibration welding, induction welding, mechanical fastening, or by any other biocompatible means that would provide for a sufficient attachment method. Tether 24 may also comprise an end portion such as a loop that is sized and configured to fit over a medical professional's thumb to allow the medical professional to single-handily slide the sheath 14 during intubation. In other embodiments, the end portion of tether 24 may comprise a hook or fastener that may allow a medical professional to single-handily slide the sheath 14 during intubation.

[0041] In some embodiments, sheath 14 may be manufactured to include tapered portion 25—being wider at the distal end 38. The tapered portion 25 of sheath 14 may be sized and configured to provide resistance against the vocal cords 62 or supraglottic structures 60 before the distal end 22 of tube 20 enters the trachea 66, as will be discussed below in reference to FIGs. 4-9. In other embodiments, where the sheath 14 is sized and configured to allow a medical professional to single-handily slide sheath 14, the sheath 14 may not include a tapered portion 25. The tapered portion 25 may be sized and configured to substantially cover the distal end 22 of tube 20, including beveled portion 23, while still allowing for an air/oxygen mixture or anesthetic gas to flow through the endotracheal tube 20, as shown in FIG. 3. The degree of taper, curvature, and/or linearity at different parts of the sheath 14 may vary. For example, the distal end 38 of sheath 14 may be tapered differently or opposite, or may be generally symmetrical, without substantial taper from one end to the other. Likewise, other sheath 14 shapes having straight walls, curved walls, or combinations of straight and curved walls are possible and are within the scope of the present disclosure.

[0042] Primarily referring now to FIGs. 2, 2A, and 2B, sheath 14 is sized and configured to slide along tube 20 to a proximal position during or after intubation. As

discussed above, when distal end 38 of sheath 14 contacts the vocal cords 62 or supraglottic structures 60, the distal end 22 of tube 20 begins to slide through sheath 14. In some embodiments, a medical professional may assist the sheath 14 in sliding along tube 20 by pulling tether 34 or the proximal end 32 of sheath 14. Sheath 14 may then be secured in a scrunched position to tube 20 proximal to the mouth 74 of patient 78. Sheath 14 may be secured with tether 34 or by other means such as adhesive tape or mechanical attachments such as a clip, hook, or fastener. A medical professional may alternatively cut or remove sheath 14 from tube 20. Sheath 14 is void of exposed perforations that would allow sheath 14 to tear away from tube 20. Such exposed perforations are disadvantageous and have been known to harbor microbes and bacteria that are transferred to airway 88 of patient 78 during intubation, leading to increased patient care cost. In other embodiments, sheath 14 may be removed by sliding it over the proximal end 24 of tube 20. The sheath may also remain positioned proximal to vocal cords 62 in airway 88.

[0043] Sheath 14 may be formed from materials having suitable mechanical properties resistant to punctures, tears, pin holes, and chemical properties to provide for flexibility, as well as biocompatibility. The materials may include polyurethane or polyurethane-based compositions having suitable mechanical and chemical properties, such as Gore-Tex (e-polytetrafluoroethylene). Other materials may be suitable that exhibit properties enabling them to be processed into sheath 14. Sheath 14 material may comprise, for example, polypropylene, low-density polyethylene, polyamide, polyvinyl chloride, polyethylene terephthalate, silicone, neoprene, or polyisoprene. Copolymer admixtures for modifying the characteristics of the sheath 14 material may also be used, including low density polyethylene and ethylene-vinylacetate copolymer, or blends of the above mentioned materials, or other suitable materials that would be readily apparent to a person having ordinary skill in the art after having read the present disclosure. Examples of suitable

polymeric compositions may include polymethylmethacrylate, polystyrene or vinyls (such as polyvinyl chloride and polyvinylacetate), polyacrylonitrile, polyamide (such as nylon), polycarbonate, polyesters (such as polyethylene terephthalate), polyolefins (such as polyethylenes and polypropylenes).

[0044] In some embodiments, it may be desirable to form sheath 14 from an antimicrobial material or for sheath 14 to include a microbial control layer (not shown). Sheath 14 or microbial control layer may be formed from hydrophobic polymers including a hydrophilic polymer or other suitable antimicrobial materials. The microbial control layer may comprise a metal, such as gold, copper, or silver that exhibits antimicrobial properties. In addition, the microbial control layer may include an acrylamide polymerization solution (i.e., polyacrylamide solution) that may be polymerized and crosslinked by thermal initiation such as ultraviolet radiation. The pore size of the solution may be controlled by altering the amount of crosslinking and the percent of solids in the monomer solution. The microbial control layer may be any suitable material having an appropriate pore size substantially smaller than most bacteria. In some embodiments, an appropriate pore size is less than about 5 microns or less than about 0.2 microns. Pore size may be defined as the average range of diameters of pores in a material, and is typically determined by the average dimensions of the smallest particles passing through the material.

[0045] The microbial control layer may be applied to sheath 14 by dipping the sheath 14 into a polyacrylamide solution. The thickness of the microbial control layer may be altered by varying the number of times or duration that sheath 14 is dipped into the polyacrylamide solution. The microbial control layer may be applied to both the elongated inner portion 36 and outer portion 37 of sheath 14. The microbial control layer may also be extruded, molded, co-extruded, blow-molded, electrostatically applied, or sprayed onto sheath 14.

[0046] In some embodiments, sheath 14 or the microbial control layer may have reflective properties. For example, sheath 14 or the microbial control layer may comprise antimicrobial metal having sufficient reflective properties. Accordingly, in some embodiments, a medical professional may be able to detect sheath 14 in airway 88 by ultrasonography.

[0047] Turning now primarily to FIGs. 4-6 illustrating plain views of an exemplary protective sheath 14 and endotracheal tube assembly 10 before having the distal end 22 of tube 20 pass through the vocal cords 62 of patient 78. As shown in FIG. 4, initially, the distal end 22 of tube 20 and protective sheath 14 are positioned through mouth 74, over tongue 70, and into airway 88 of patient 78. To help protect the distal end 22 of endotracheal tube 20 from microbes or other contaminants during intubation, sheath 14 may be positioned to protect the distal end 22 of tube 20. As the distal end 22 of tube 20 enters the supraglottic area 60 of patient 78, the medical professional may use various devices (not shown) to improve the line of sight and to help insure that the distal end 22 of tube 20 does not enter esophagus 68. Such devices may include, for example, laryngoscopes, flexible fiberoptic bronchoscopes, or video laryngoscopes.

[0048] FIG. 5 shows a partial plain view of sheath 14 and endotracheal tube assembly 10 after the distal end 22 of tube 20 passes through the vocal cords 62 of patient 78. Sheath 14 is sized and configured to slide along tube 20 as the distal end 22 of tube 20 enters trachea 66. As shown, tapered portion 25 may be sized and configured to help prevent sheath 14 from passing through vocal cords 62 or surrounding supraglottic area 60 and entering trachea 66. As tapered portion 25 contacts vocal cords 62 or surrounding supraglottic area 60, tube 20 slides through sheath 14. In some embodiments, sheath 14 may comprise a textured portion (not shown) to increase the frictional engagement between sheath 14 and airway 88—including the vocal cords 62, trachea 66, or supraglottic area 60. The textured portion being

configured to still allow a medical professional to easily remove sheath 14 from airway 88. The textured portion may comprise closely spaced regular or random grooves forming a geometric pattern on at least a portion of sheath 14. The geometric patterning may be applied to sheath 14 by chemical etching, mechanical etching, photo-etching, and/or plasma etching. In one embodiment, the textured area may comprise less than 100% of the total surface of sheath 14. In another embodiment, the textured area may comprise less than 80% of the total surface of sheath 14. In another embodiment, the textured area may comprise less than 50% of the total surface of sheath 14. The textured portion may be in combination with the tapered portion 25 or in place of the tapered portion 25. The textured portion may comprise a microbial control layer, as discussed above.

[0049] FIG. 6 shows a partial plain view of sheath 14 after the distal end 22 of tube 20 is positioned within trachea 66 and sheath 14 is retracted to a position proximal to the mouth 74 of patient 78. As shown, cuff 12 and the distal end 22 of tube 20 are positioned below vocal cords 62. Once positioned below the vocal cords 62, a medical professional may inflate, or finish inflating, cuff 12 with syringe 16 by delivering a fluid, such as air, through conduit 26 operatively associated with port 28. As cuff 12 is inflated, a seal is created between the walls of trachea 66 and rolling cuff 12. The seal allows a ventilator to more efficiently provide an air/oxygen mixture or anesthetic gas to patient 78 without air leaks through tube 20. Cuff 12 may also act as an anchor below the vocal cords 62.

[0050] Primarily referring now to FIGs. 7-9, showing coronal cross-sectional views taken along portions of FIGs. 4-6 and illustrating the distal end 22 of tube 20 positioned in various sections of airway 88 and trachea 66. Turning first to FIG. 7 showing a coronal cross-sectional view of FIG. 4 illustrating the distal end 22 of tube 20 positioned in the supraglottic area 60 of patient 78. As distal end 22 of tube 20 draws closer to vocal cords 62, the tapered portion 25 of sheath 14 contacts vocal cords 62 and/or supraglottic structure 60

(epiglottis 76), thereby initiating the transition of sheath 14 towards the proximal end 24 of tube 20.

[0051] As shown in FIG. 8, sheath 14 continues to transition towards the proximal end 24 of tube 20 as cuff 12 enters the trachea 66. FIG. 9 shows an inflated cuff 12 positioned below the vocal cords 62 within trachea 66 and above carina 82, as well as sheath 14 transitioning towards the proximal end 24 of tube 20. Once inflated, cuff 12 may substantially fill the area of the trachea 66 below the vocal cords 62 to form a seal with trachea 66 to provide ventilation and oxygenation to lungs 92 through bronchi 84. Trachea 66 comprises walls having cartilage rings 94 separated by softer intervening tissue 90 such as, for example, fibrous tissue, muscular fibers, glands, and mucous membranes. Cartilage rings 94 may vary in number from about 15 to 20. Cartilage rings 94 may be spaced about 1 to 4 millimeters apart along the trachea 66. Rolling cuff 12 may be configured to conform to the walls of trachea 66 upon inflation and positioned within trachea 66 depending on the number of cartilage rings 94 and spacing between cartilage rings 94.

[0052] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, alternatives, and equivalents falling within the spirit and scope of the invention as defined by the following claims.

What is claimed is:

1. A medical device, comprising:
a protective sheath having a proximal end and a distal end, an inner diameter forming an inner elongated portion, an outer diameter forming an outer elongated portion, and a distal portion, wherein the distal portion of the protective sheath protects a distal portion of an endotracheal tube, positioned adjacent to the inner elongated portion of the sheath, before and during intubation of a patient.
2. The medical device of claim 1, wherein the sheath further comprises a tether extending from distal end of the sheath.
3. The medical device of claim 2, wherein the tether comprises an end portion for sliding the sheath along the endotracheal tube during intubation.
4. The medical device of claim 1, wherein the distal portion of the protective sheath is tapered.
5. The medical device of claim 1, wherein the sheath further comprises a microbial control layer having a pore size of less than 5 microns.
6. The medical device of claim 5, wherein the microbial control layer comprises a material selected from the group consisting of ammonio methacrylate, dimethylaminoethyl-methacrylate, and polyethyleneimine.

7. The medical device of claim 1, wherein the sheath further comprises a microbial control layer having a pore size of less than 0.2 microns.
8. The medical device of claim 7, wherein the microbial control layer comprises a material selected from the group consisting of ammonio methacrylate, dimethylaminoethyl-methacrylate, and polyethyleneimine.
9. The medical device of claim 1, wherein the sheath covers a distal cuff attached to the endotracheal tube.
10. The medical device of claim 1, wherein the sheath comprises a material selected from the group consisting of polyvinyl chloride, silicone, neoprene, polyisoprene, polyurethane, polyethylene terephthalate, and low-density polyethylene.
11. A method of manufacturing a medical device, comprising:
providing a sheath for protecting an endotracheal tube before and during intubation, wherein the sheath comprises a proximal end, a distal end having a tapered portion, an inner diameter forming an elongated inner portion for covering the endotracheal tube, and an outer diameter forming an elongated outer portion.
12. The method according to claim 11, wherein the sheath further comprises a tether.
13. The method according to claim 11, further comprising applying a microbial control layer to the elongated outer portion of the sheath, wherein the microbial control layer has a pore size of less than 5 microns.

14. The method according to claim 11, further comprising applying a microbial control layer to the elongated outer portion of the sheath, wherein the microbial control layer has a pore size of less than 0.2 microns.

15. A medical device, comprising:

a protective sheath having a proximal end and a distal end, an inner diameter forming an inner elongated portion, an outer diameter forming an outer elongated portion, and a distal tapered portion, wherein the protective sheath protects a distal portion of an endotracheal tube, positioned adjacent to the inner elongated portion of the sheath, before and during intubation of a patient, and wherein the sheath comprises a material having a pore size of less than 5 microns.

16. The medical device of claim 15, wherein the sheath further comprises a tether extending from distal end of the sheath.

17. The medical device of claim 15, wherein the sheath material comprises a material selected from the group consisting of ammonio methacrylate, dimethylaminoethyl-methacrylate, and polyethyleneimine.

18. The medical device of claim 15, wherein the material pore size is less than 0.2 microns.

19. The medical device of claim 15, wherein the sheath covers a distal cuff attached to the endotracheal tube.

20. The medical device of claim 15, wherein the sheath further comprises a material selected from the group consisting of polyvinyl chloride, silicone, neoprene, polyisoprene, polyurethane, polyethylene terephthalate, and low-density polyethylene.

21. A medical device, comprising:

a protective sheath having a proximal end and a distal end, an inner diameter forming an inner elongated portion, an outer diameter forming an outer elongated portion, and a textured portion to increase frictional engagement between the protective sheath and airway of a patient, wherein the protective sheath protects a distal portion of an endotracheal tube, positioned adjacent to the inner elongated portion of the sheath, before and during intubation of the patient.

22. The medical device of claim 21, wherein the sheath further comprises a microbial control layer having a pore size of less than 5 microns.

23. The medical device of claim 22, wherein the microbial control layer comprises a material selected from the group consisting of ammonio methacrylate, dimethylaminoethyl-methacrylate, and polyethyleneimine.

24. The medical device of claim 21, wherein the sheath further comprises a microbial control layer having a pore size of less than 0.2 microns.

25. The medical device of claim 24, wherein the microbial control layer comprises a material selected from the group consisting of ammonio methacrylate, dimethylaminoethyl-methacrylate, and polyethyleneimine.

26. The medical device of claim 21, wherein the sheath covers a distal cuff attached to the endotracheal tube.

27. The medical device of claim 21, wherein the sheath comprises a material selected from the group consisting of polyvinyl chloride, silicone, neoprene, polyisoprene, polyurethane, polyethylene terephthalate, and low-density polyethylene.

28. A method of manufacturing a medical device, comprising:

providing a sheath for protecting an endotracheal tube before and during intubation, wherein the sheath comprises a proximal end, a distal end having a textured portion, an inner diameter forming an elongated inner portion for covering the endotracheal tube, and an outer diameter forming an elongated outer portion.

29. The method according to claim 28, further comprises a material having a pore size of less than 5 microns.

30. The method according to claim 28, further comprising a material having a pore size of less than 0.2 microns.

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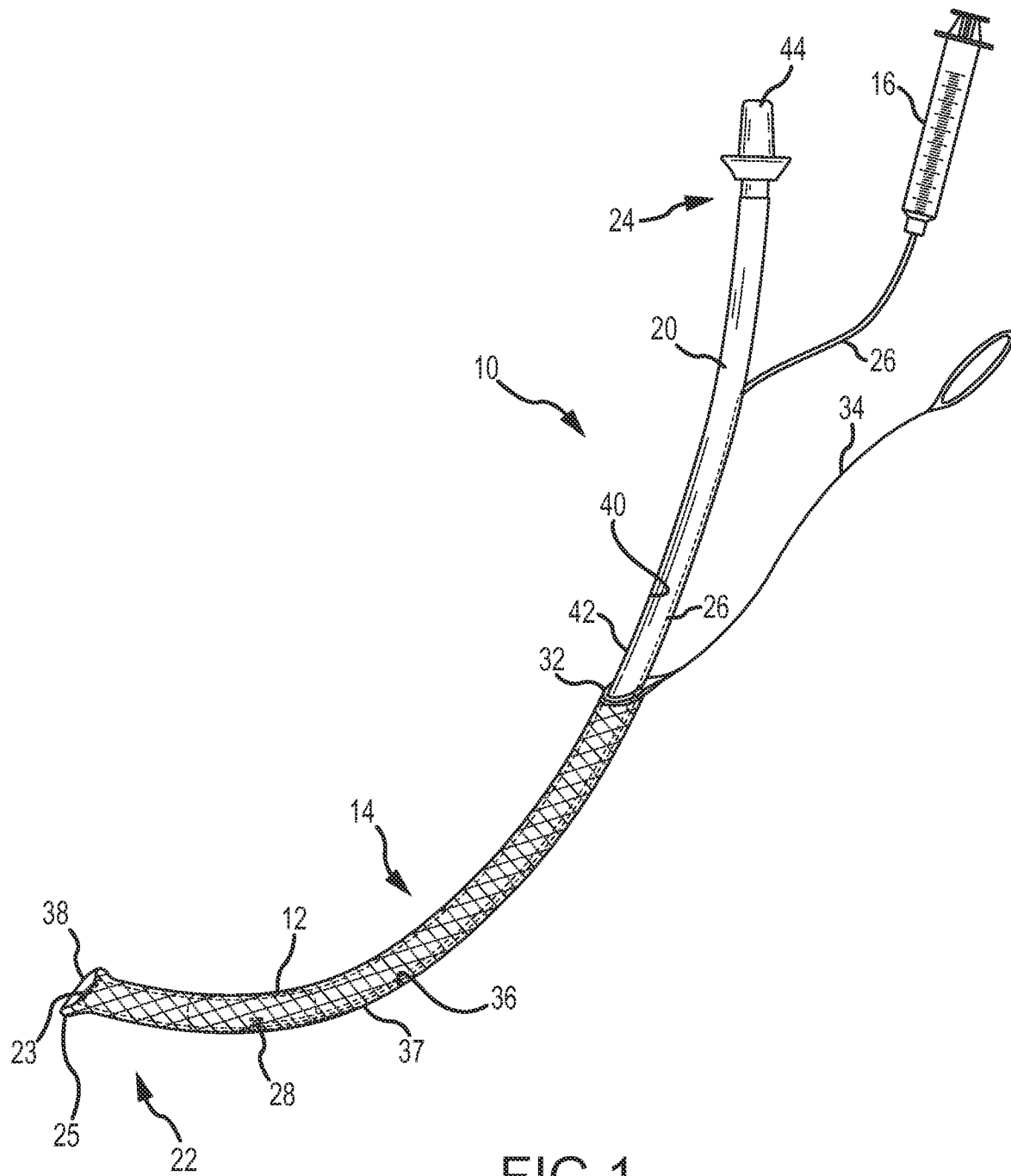


FIG.1

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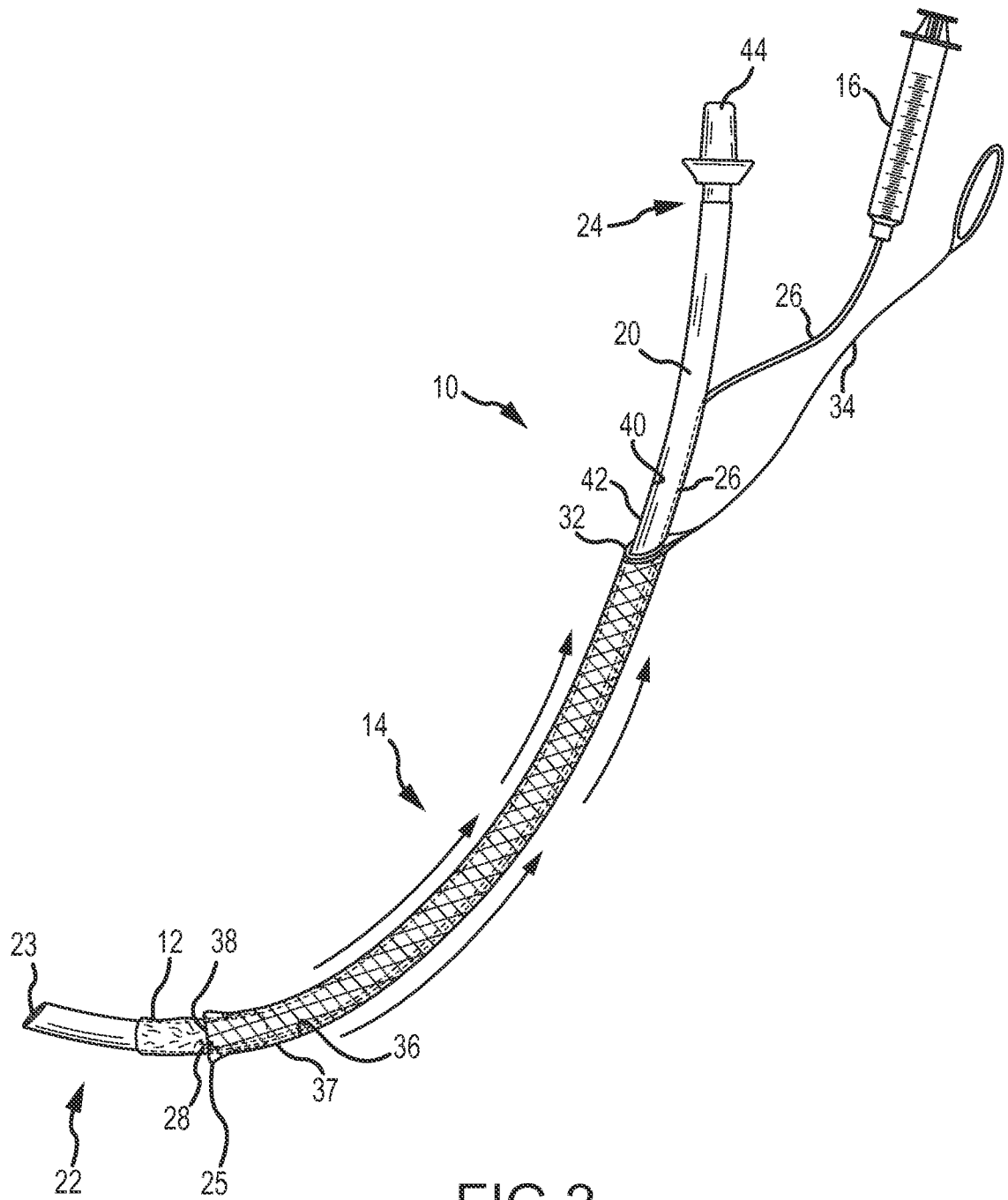


FIG.2

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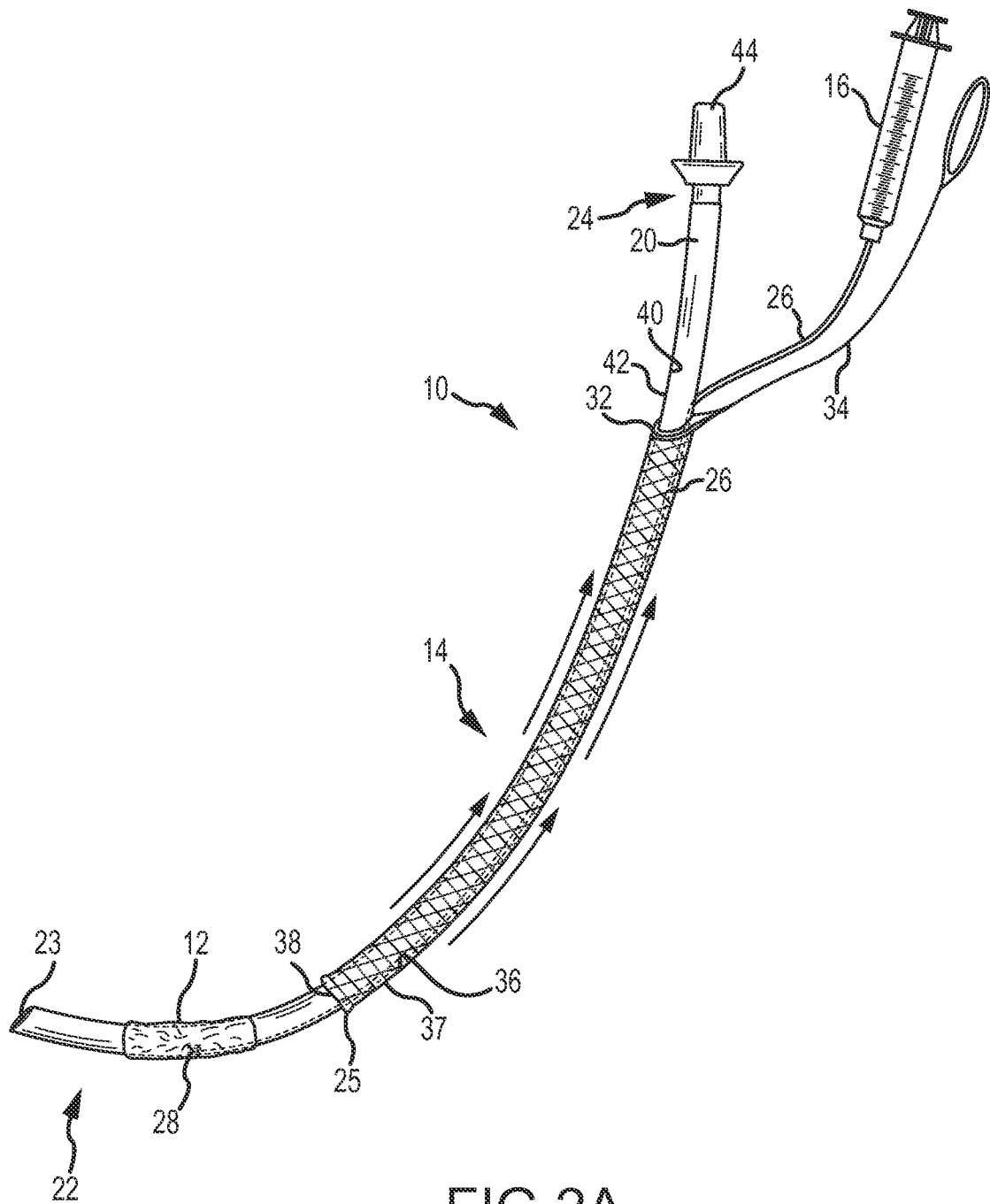


FIG.2A

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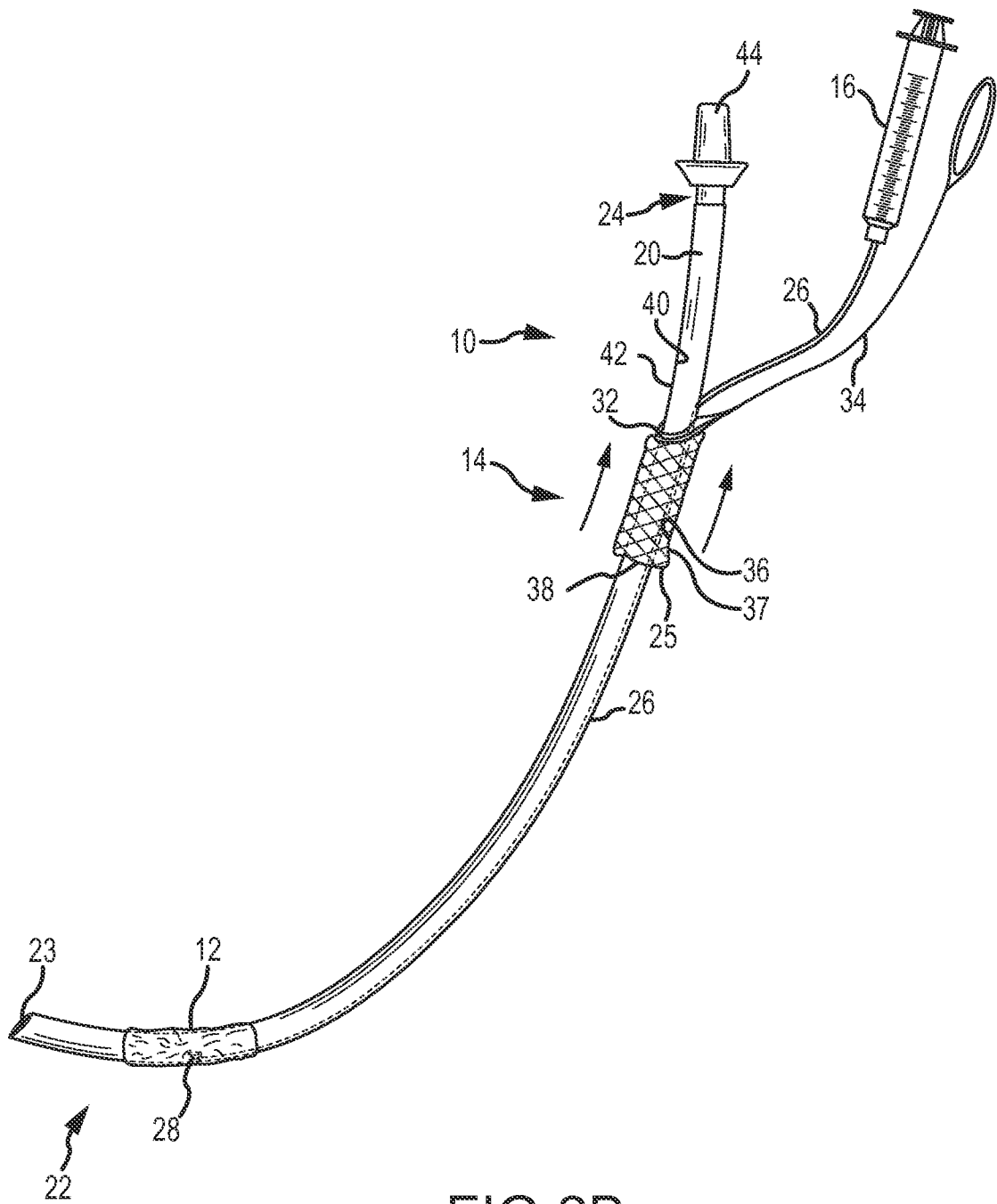


FIG.2B

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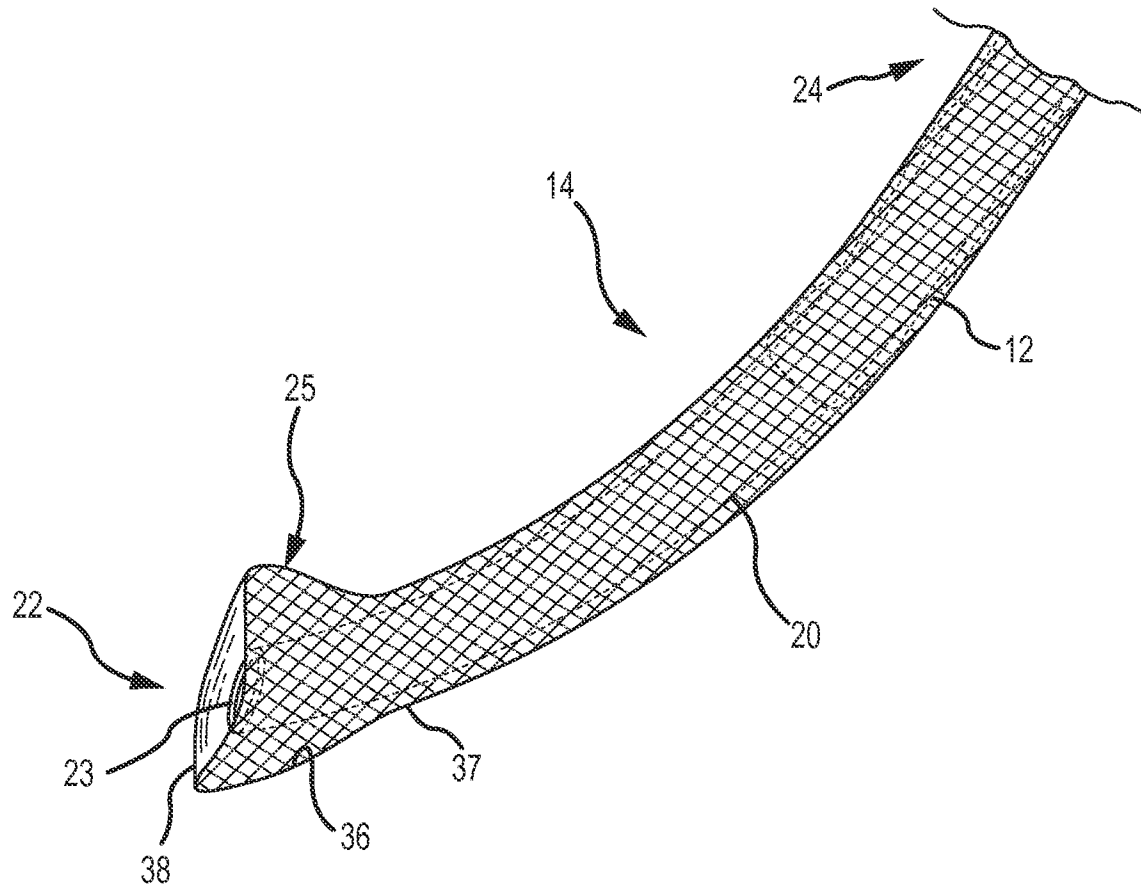
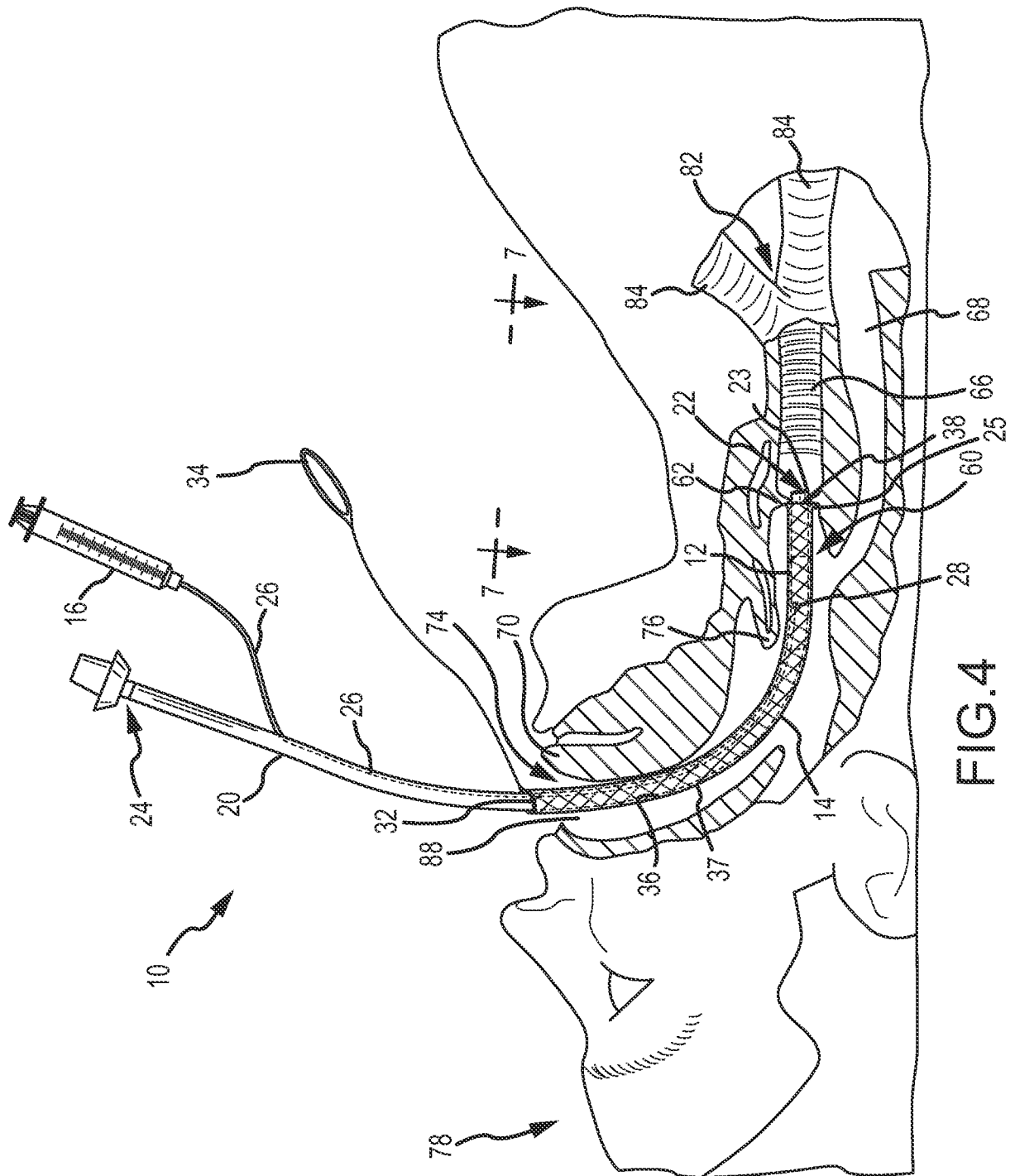


FIG.3

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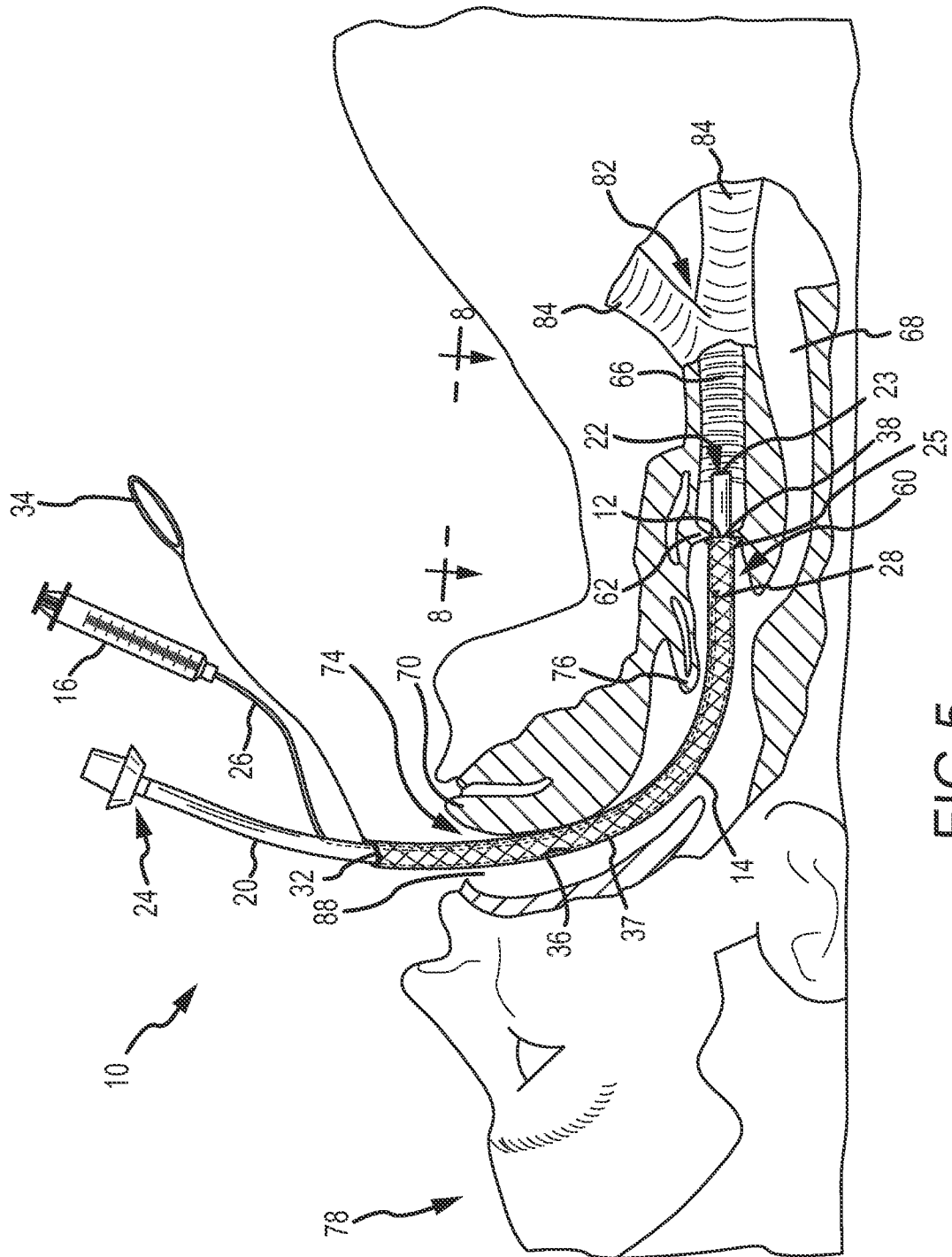
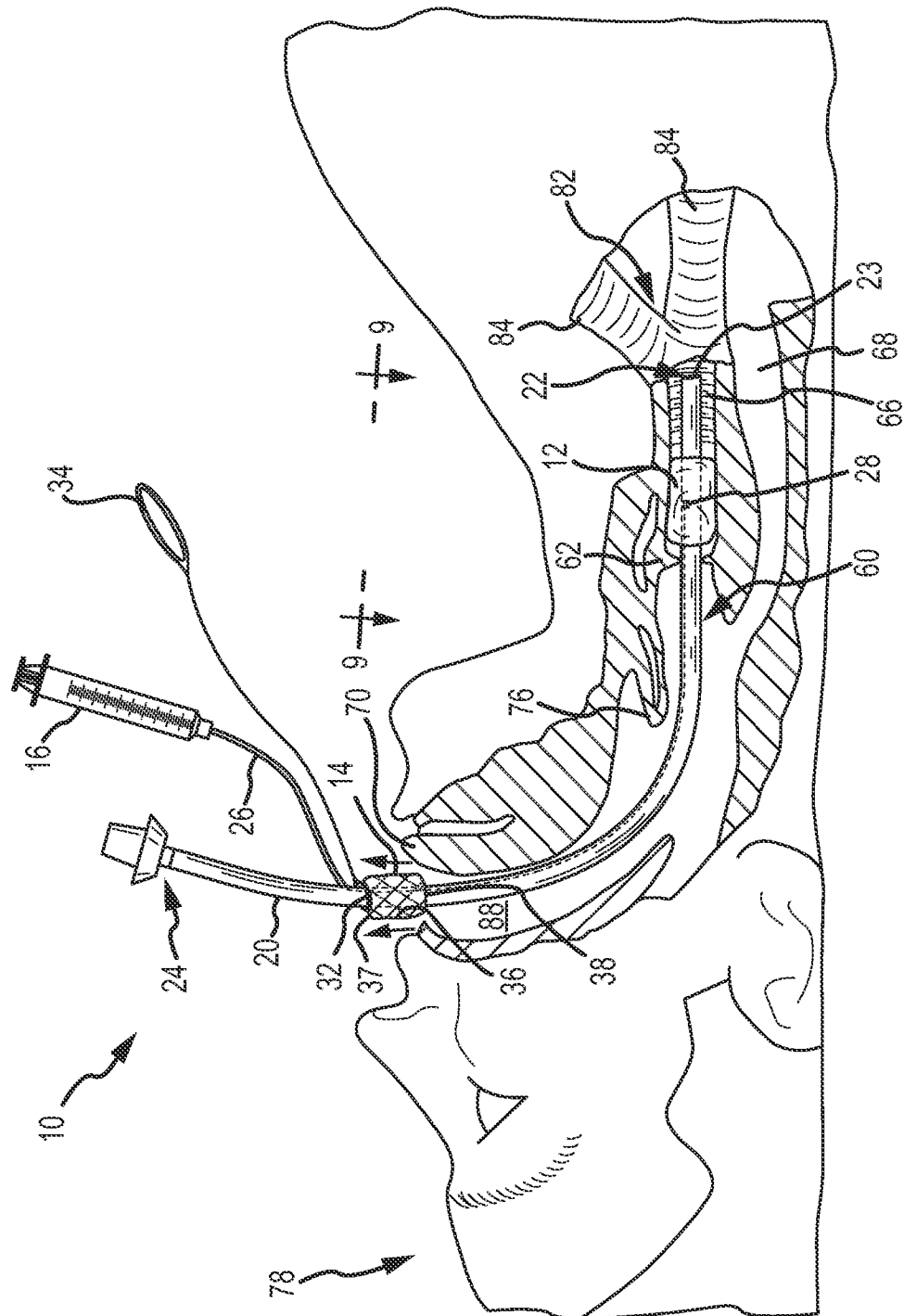


FIG.5



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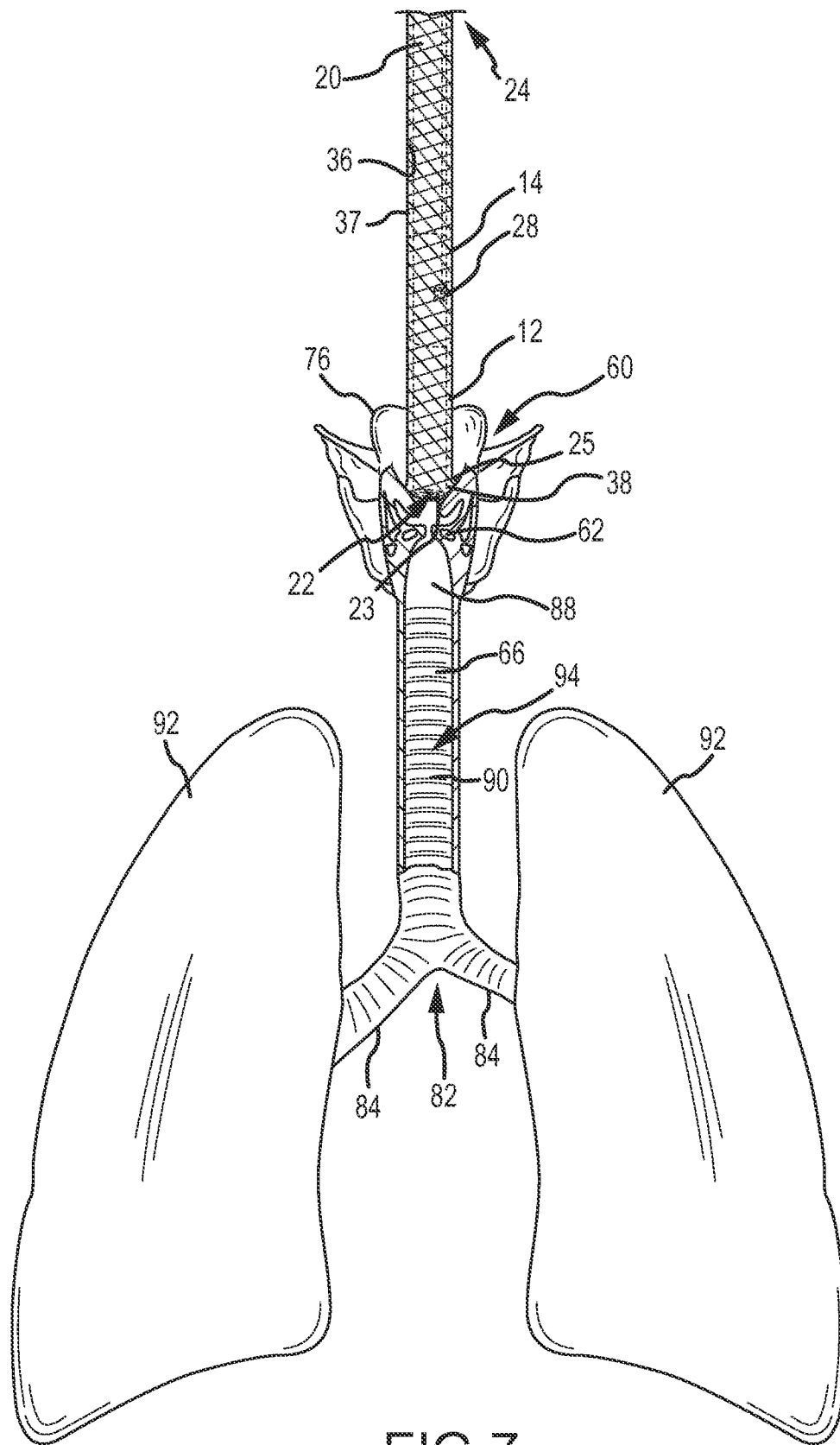


FIG. 7

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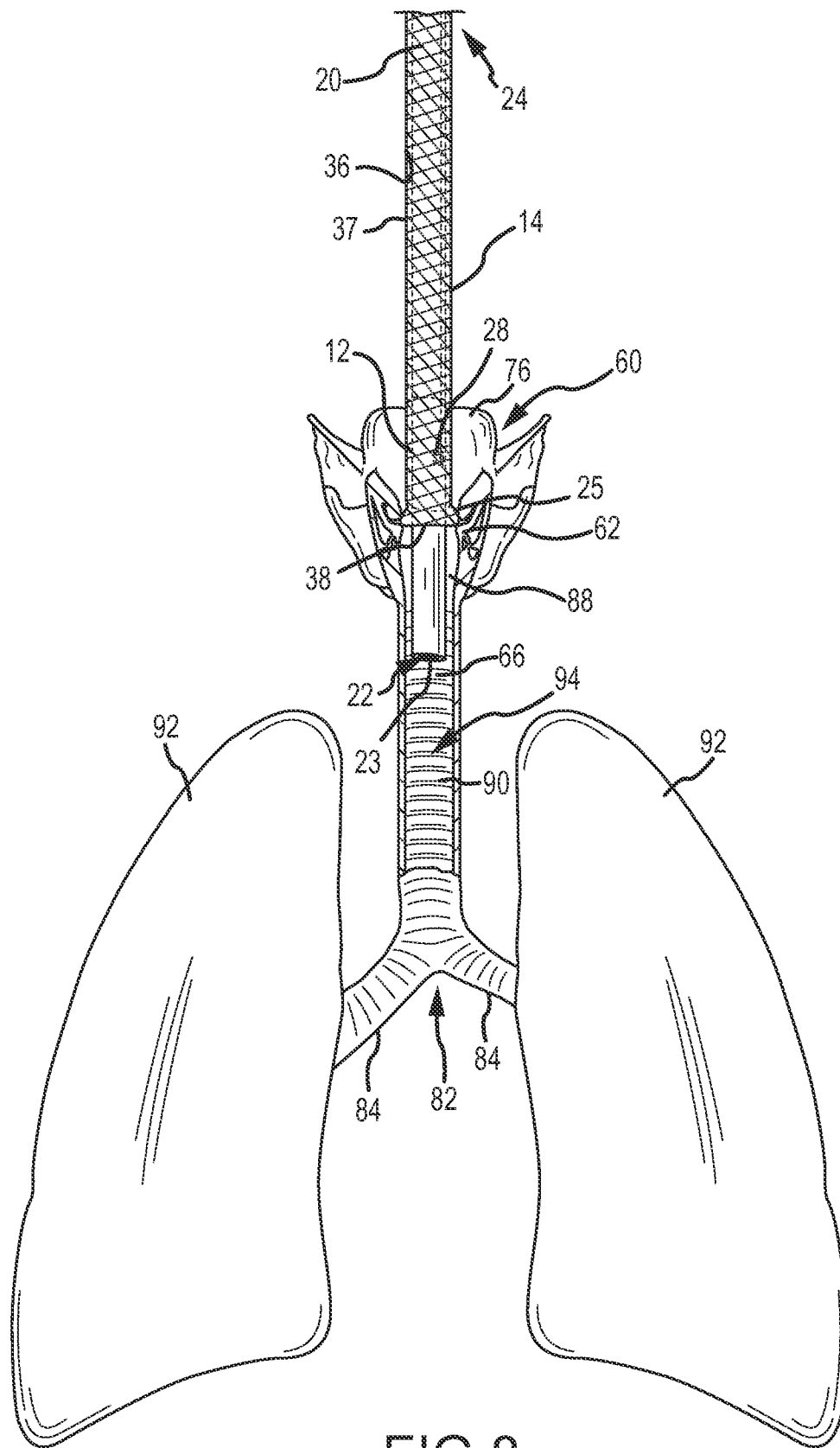
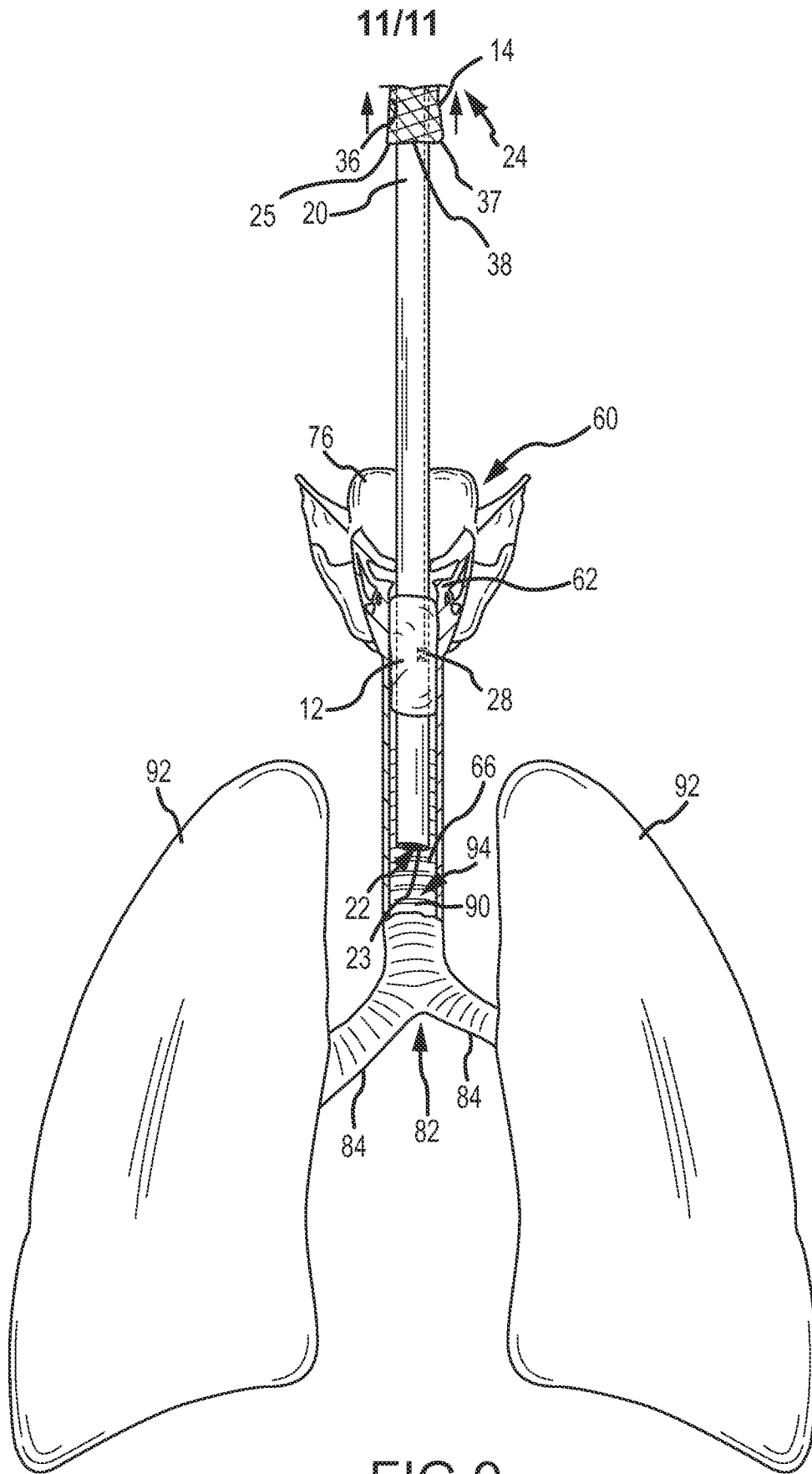


FIG. 8



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/047775

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 16/04 (2014.01)

CPC - A61M 16/04 (2014.10)

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)

IPC(8) - A61M 16/00, 16/04 (2014.01)

CPC - A61M 16/04, 16/0402, 16/0434, 16/0443, 16/0463 (2014.10)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC- 128/207.14, 207.15 (keyword delimited)

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

PatBase, Google Patents, Google Scholar

Search terms used: sheath, endotracheal tube, tether, sliding, pore size, insertion, sleeve, intubation, protection, contamination

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,065,755 A (KLAFTA) 19 November 1991 (19.11.1991) entire document	1-4, 9-12, 21, 26-28
Y		5-8, 13-20, 22-25, 29, 30
Y	US 2008/0142016 A1 (COLBURN et al) 19 June 2008 (19.06.2008) entire document	5-8, 13-20, 22-25, 29, 30
A	US 4,655,214 A (LINDER) 07 April 1987 (07.04.1987) entire document	1-32

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

* Special categories of cited documents:

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

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"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

09 November 2014

Date of mailing of the international search report

11 DEC 2014

Name and mailing address of the ISA/US

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