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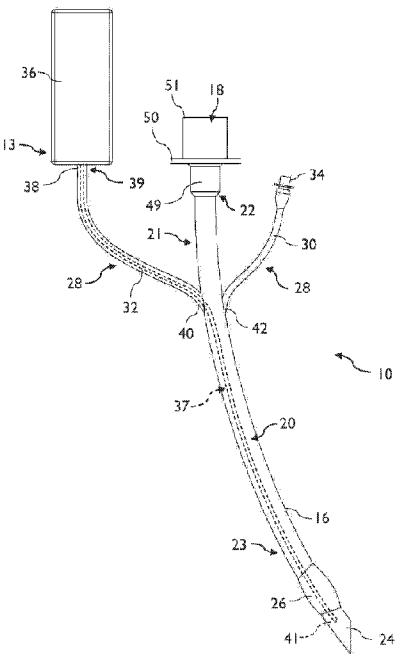
(54) Titre : PROCEDES ET APPAREIL POUR ADMINISTRER UN RAYONNEMENT ELECTROMAGNETIQUE THERAPEUTIQUE NON-ULTRAVIOLET POUR UN TUBE TRACHEAL

(54) Title: METHODS AND APPARATUS TO DELIVER THERAPEUTIC NON-ULTRAVIOLET ELECTROMAGNETIC RADIATION FOR AN ENDOTRACHEAL TUBE



(57) Abrégé/Abstract:
A therapeutic endotracheal tube assembly is provided for insertion into a patient's trachea to ventilate, to maintain patency of the patient's airway, and to deliver therapeutic electromagnetic radiation (EMR) to the patient. The therapeutic endotracheal tube assembly has an endotracheal tube and an EMR delivery system. The EMR delivery system has an EMR source for emitting non-ultraviolet, therapeutic EMR having intensity sufficient to activate desired therapeutic properties within the patient and an EMR conduction line conducive to the propagation of EMR from the EMR source along the endotracheal tube. The EMR conduction line is removably insertable into the endotracheal tube. The therapeutic endotracheal tube assembly may be custom made or may be constructed by retrofitting a removably insertable EMR delivery system to an existing endotracheal tube.

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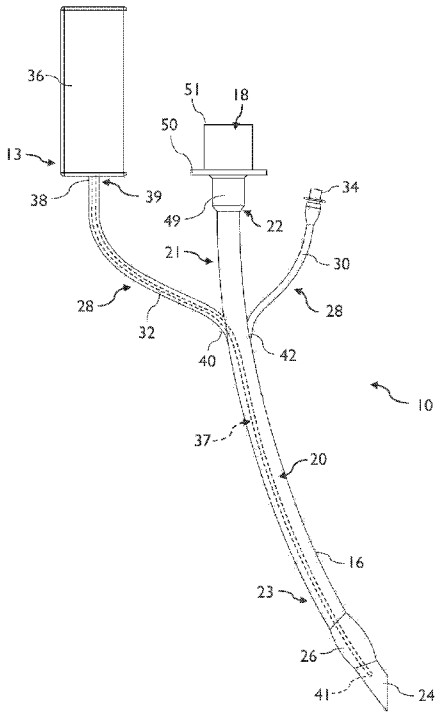
(54) Title: METHODS AND APPARATUS TO DELIVER THERAPEUTIC NON-ULTRAVIOLET ELECTROMAGNETIC RADIATION FOR AN ENDOTRACHEAL TUBE

FIG. 1



(57) Abstract: A therapeutic endotracheal tube assembly is provided for insertion into a patient's trachea to ventilate, to maintain patency of the patient's airway, and to deliver therapeutic electromagnetic radiation (EMR) to the patient. The therapeutic endotracheal tube assembly has an endotracheal tube and an EMR delivery system. The EMR delivery system has an EMR source for emitting non-ultraviolet, therapeutic EMR having intensity sufficient to activate desired therapeutic properties within the patient and an EMR conduction line conducive to the propagation of EMR from the EMR source along the endotracheal tube. The EMR conduction line is removably insertable into the endotracheal tube. The therapeutic endotracheal tube assembly may be custom made or may be constructed by retrofitting a removably insertable EMR delivery system to an existing endotracheal tube.

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METHODS AND APPARATUS TO DELIVER THERAPEUTIC NON-ULTRAVIOLET ELECTROMAGNETIC RADIATION FOR AN ENDOTRACHEAL TUBE

RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Application No. 62/154,789 that was filed April 30, 2015, for an invention titled METHODS AND APPARATUS TO INACTIVATE INFECTIOUS AGENTS ON AN ENDOTRACHEAL TUBE. This application also claims the benefit of United States Provisional Application No. 62/292,028 that was filed February 5, 2016, for an invention titled METHOD AND APPARATUS FOR REMOVABLE CATHETER VISUAL LIGHT STERILIZATION SYSTEM.

[0002] This application is related to a co-pending application entitled METHODS AND APPARATUS TO INACTIVATE INFECTIOUS AGENTS ON A CATHETER RESIDING IN A BODY CAVITY, U.S. Application Serial No. 13/801,750, filed March 13, 2013.

TECHNICAL FIELD

[0003] The present invention is a method and apparatus to provide therapeutic doses of non-ultraviolet light and/or sterilizing doses of non-ultraviolet light to stimulate healthy cell growth causing a healing effect and/or to inactivate infectious agents residing on, within, or generally around an endotracheal tube while said endotracheal tube is residing within a body cavity.

BACKGROUND

[0004] Endotracheal tubes are medical devices used to provide mechanical ventilation for incapacitated patients. Unfortunately, they commonly cause hospital-acquired pneumonia (HAP). These devices cause infections in 91,000-126,000 patients every year and are the leading cause of death among hospital-acquired infections (Scheld WM. Developments in the pathogenesis, diagnosis and treatment of nosocomial pneumonia. Surg Gynecol Obstet 1991; 172 Suppl:42).

[0005] The current first-line standard of care treatment is antibiotics (American Thoracic Society, Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am J Respir Crit

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Care Med 2005; 171:388). However, establishing the diagnosis of ventilator-associated pneumonia (VAP) can be difficult due to concomitant etiologies and symptoms, leading to increased mortality. Additionally, the prevalence of drug-resistant bacteria often necessitates a more toxic second-line antibiotic treatment and, due to a greater side-effect profile, further increases the risk to patient safety.

[0006] Endotracheal tubes are known that function only to secure the airway and provide ventilation for the intubated patient. Various hydrophobic, antibiotic, and/or anti-inflammatory coatings for endotracheal tubes are also known. Examples of these coatings include antibiotic agents like chlorhexidine or silver. This coating is intended to inhibit bacterial and fungal colonization of the device. However, these proposals are only marginally effective in-vivo and are unable to prevent numerous infections and deaths.

[0007] There are also known methods for providing visualization at the tip of the endotracheal tube. While possibly helpful for the device insertion, this has not become a standard of care due to simpler methods being developed. This also does nothing to reduce the infection rates.

[0008] The use of ultraviolet (UV) light to reduce the prevalence of infection is known. Unfortunately, UV light is well known to cause damage to living cells (Rittié. "UV-light-induced signal cascades and skin aging." Ageing research reviews 1.4 (2002): 705-720).

[0009] Unfortunately, these methods and solutions fail to offer a reduction in hospital-acquired infections. This is due not only to the difficulty in diagnosing HAP in the midst of concomitant etiologies, but also to the high clinical prevalence of drug resistant microorganisms. Accordingly, there exists a need for a method and apparatus for delivering non-antibiotic, bactericidal therapeutics in-vivo, and for such a method and apparatus to use novel technology in delivering safe, effective, and reproducible disinfection.

SUMMARY OF THE INVENTION

[0010] The invention of the present disclosure comprises of a method and apparatus for delivering therapeutic doses in-vivo to stimulate healthy cell growth causing a healing effect and/or to inactivating infectious agents on or within an endotracheal tube. In particular, the exemplary embodiments of this disclosure allow for therapeutic treatments that stimulate healthy

cell growth enhancing healing and/or that inactivate infectious agents while the endotracheal tube is residing within a patient's body cavity. Generally, this disclosure relates to an endotracheal tube assembly that incorporates the delivery of electromagnetic radiation (EMR) therapy in addition to the functions of existing standard of care endotracheal tubes (securing airway, providing a passage for mechanical ventilation, etc.). The endotracheal tube assembly includes an endotracheal tube with an associated EMR source that provides non-ultraviolet, therapeutic EMR of sufficient fluency to inactivate one or more infectious agents and/or to stimulate healthy cell growth causing a healing effect.

[0011] For the purposes of this disclosure the use of the term "therapeutic" should be understood to mean of or relating to the treatment of disease, including infectious agents, as well as serving or performed to maintain health, including enhancing healthy cell growth.

[0012] It should also be understood that the exemplary embodiments of this disclosure include retrofitting a EMR delivery system to an existing standard endotracheal tube where the EMR delivery system is permanently attached to the endotracheal tube or where the EMR delivery system is removably insertable into the endotracheal tube, as well as including the use of a custom-made endotracheal tube that incorporates the EMR delivery system into the structure of the endotracheal tube. For a rapid, retrofit connection of the EMR delivery system onto the endotracheal tube a quick-connect coupling may be used and/or the insertable portion of the EMR delivery system may move freely and axially relative to the endotracheal tube.

[0013] This disclosure also provides methods and apparatuses for effectively sterilizing the body surface for the area in, on, or around the endotracheal tube. This is done through use of EMR at sufficient intensities capable of inactivation of infectious agents. This source can be from a single or group of EMR sources including, but not limited to, a light emitting diode, a semiconductor laser, a diode laser, an incandescent and fluorescent light source. This EMR source provides non-ultraviolet, sterilizing EMR providing one or more wavelengths in the range of approximately 380 nm to approximately 900 nm. In order to provide sufficient inactivation of infectious species each EMR wavelength should be of a narrow spectrum and centered around one wavelength from the group, and has intensity sufficient to inactivate one or more infectious agents. This group includes several wavelengths centered about: 400 nm, 405 nm, 415 nm, 430 nm, 440 nm, 455 nm, 470 nm, 475 nm, 660 nm, and 808 nm.

[0014] Of particular interest to this endotracheal tube assembly is the use of light between 380 and 900 nm wavelengths. Additionally, the intensity and power of the light emitted is particularly suitable for the inactivation of infectious agents, thus a range of fluency covering 0.1 J/cm^2 to 1 kJ/cm^2 and a range of powers from 0.005 mW to 1 W, and power density range covering 1 mW/cm^2 and 1 W/cm^2 are of interest for these device assemblies and methods.

[0015] The EMR delivery system directs the EMR lengthwise along the wall of said flexible tube in the plane of the flexure thereof for emission of the EMR internal and/or external to the endotracheal tube body. In most cases, EMR delivery system may be inserted such that its forward end terminates toward the forward end of the flexible, endotracheal tube body.

[0016] For each exemplary embodiment, the endotracheal tube assembly and method for disinfection could be utilized in an adjustable or predetermined duty cycle. If treatments began immediately after sterile procedure was initiated, device related infections may be inhibited. This includes device related biofilm growth.

[0016a] In another embodiment of the present invention there is provided a therapeutic endotracheal tube assembly for insertion into a patient's trachea to ventilate, to maintain patency of the patient's airway, and to deliver therapeutic electromagnetic radiation (EMR) to the patient, the therapeutic endotracheal tube assembly comprising: an endotracheal tube having: a) a lumen defined by a tube wall, an upper tube portion having a proximate end, and a lower tube portion having a forward end for insertion into the patient's trachea, and b) an inflatable cuff surrounding the tube wall proximate the forward end; and an EMR delivery system comprising: a) an EMR source for emitting non-ultraviolet, therapeutic EMR having intensity sufficient to activate desired therapeutic properties within the patient, the EMR source further comprises a range of fluency covering 0.1 J/cm2 to 1 kJ/cm2, and a range of powers from 0.005 mW to 1 W, and power density range covering 1 mW/cm2 to 1 W/cm2; b) an EMR conduction line conducive to the propagation of EMR from the EMR source along the endotracheal tube, the EMR conduction line having a coupling end and a distal end and being insertable into the endotracheal tube to deliver non-ultraviolet, therapeutic EMR within the patient at sufficient intensity to activate desired therapeutic properties; and c) a coupling to connect the EMR source to the coupling end of the EMR conduction line; characterised in that: the endotracheal tube further comprises a ventilator collar, the upper tube portion having a proximate end coupled to a ventilator collar; and the therapeutic endotracheal tube assembly further comprises an endotracheal adapter disposed intermediate of the ventilator collar and the ventilator, the EMR

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conduction line is disposed directly within the EMR port so that the EMR conduction line is insertable into the ventilation channel and then into the lumen of the tube body of the endotracheal tube and may be subsequently removed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] These and other features and advantages of the present disclosure will become more readily appreciated by referring to the following detailed description of exemplary embodiments when considered in connection with the accompanying drawings, which are not necessarily drawn to scale. It will be understood that said drawings depict exemplary embodiments and, therefore, are not to be considered as limiting the scope with regard to other embodiments which the invention is capable, wherein:

[0018] **FIG. 1** is a profile view, illustrating an exemplary embodiment of a custom-made endotracheal tube with side ports for an inflation cuff and for an exemplary EMR delivery system;

[0019] **FIG. 2** is a perspective view illustrating another exemplary embodiment of a custom-made endotracheal tube with a branched side port for accommodating an inflation cuff and for an exemplary EMR delivery system;

[0020] **FIG. 3** is a perspective, exploded view illustrating yet another exemplary embodiment of a custom-made endotracheal tube with a side port for an inflation cuff and showing an EMR source that fits over the ventilator collar of the endotracheal tube;

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[0021] **FIG. 4** is a profile, exploded view illustrating still another exemplary embodiment of an existing endotracheal tube that is retrofit with a port adapter to accommodate the insertion of an EMR conduction line of an EMR delivery system;

[0022] **FIG. 5** is a profile view illustrating the exemplary embodiment of FIG. 4 showing the port adapter connected to the ventilation collar of the endotracheal tube;

[0023] **FIG. 6** is a cross sectional view of the exemplary port adapter illustrating the ingress point for the EMR conduction line into a through channel within the port adapter;

[0024] **FIG. 7** is a perspective view of the exemplary port adapter of **FIGS. 4-6**;

[0025] **FIG. 8** is a cross sectional view of a lower portion of an exemplary endotracheal tube showing the insertion of an EMR conduction line within the lumen of the endotracheal tube;

[0026] **FIG. 9** is a cross sectional view of an exemplary custom-made endotracheal tube showing an embedded cuff inflating conduit and embedded optical conduits;

[0027] **FIG. 10** is a cross sectional view of yet another exemplary custom-made endotracheal tube showing an embedded cuff inflating conduit and embedded optical conduits;

[0028] **FIG. 11** is a cross sectional view of still another exemplary custom-made endotracheal tube showing an embedded cuff inflating conduit and smaller embedded optical conduits;

[0029] **FIG. 12** is a cross sectional view of yet another exemplary custom-made endotracheal tube showing an embedded cuff inflating conduit and partially embedded optical conduits;

[0030] **FIG. 13** is a cross sectional view of still another exemplary custom-made endotracheal tube showing an embedded cuff inflating conduit and secondary lumens for housing EMR conduction lines;

[0031] **FIG. 14** is a profile, sectional view illustrating an exemplary embodiment of a tripartite port adapter for connection to an endotracheal tube, wherein the tripartite port adapter accommodates the connection of various-sized ventilator connectors in either male or female engagement and also accommodates the insertion of an EMR conduction line of an EMR delivery system into the endotracheal tube; and

[0032] **FIG. 15** is a perspective view of the exemplary embodiment of an existing endotracheal tube that is retrofit with a port adapter to accommodate the insertion of an EMR conduction line of an EMR delivery system.

REFERENCE NUMERALS

endotracheal tube assembly **10**
endotracheal tube **12**
EMR delivery system **13**
lumen **14**
tube wall **16**
ventilator collar **18**
tube body **20**
upper tube portion **21**
proximate end **22**
lower tube portion **23**
forward end **24**
inflatable cuff **26**
side ports **28**
cuff inflation conduit **30**
optical conduit **32**
cuff inflation fitting **34**
EMR source **36**
EMR conduction line **37**
EMR coupling **38**
coupling end **39**
optical joinder site **40**
distal end **41**
inflation joinder site **42**
combined joinder site **44**
combining site **46**
combined conduit **48**
connection sleeve **49**
stop flange **50**
engagement cylinder **51**
EMR directing ring **52**
cylindrical aperture **54**
centerline **56**
inflation cuff conduit **58**
internal surface **60**
external surface **62**
distal optical conduit(s) **64 (A-I)**
optical conduit channel **66**
endotracheal adapter **68**
adapter body **69**
EMR port **70**
ventilator fitting end **71**
engagement end **72**
adapter stop flange **74**
ventilation channel **75**
EMR illumination **76**
secondary port **78**
first inner diameter **80**
first outer diameter **82**
second inner diameter **84**
second outer diameter **86**

DETAILED DESCRIPTION

[0033] Various exemplary embodiments of the present disclosure are described more fully hereafter with reference to the accompanying drawings. These drawings illustrate some, but not all of the embodiments of the present disclosure. It will be readily understood that the components of the exemplary embodiments, as generally described and illustrated in the Figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of the exemplary embodiments of the apparatus, system, and method of the present disclosure, as represented in FIGS. 1 through 15, is not intended to limit the scope of the invention, as claimed, but is merely representative of exemplary embodiments.

[0034] The phrases "connected to," "coupled to" and "in communication with" refer to any form of interaction between two or more entities, including mechanical, electrical, magnetic, electromagnetic, fluid, and thermal interaction. Two components may be coupled to each other even though they are not in direct contact with each other. The term "abutting" refers to items that are in direct physical contact with each other, although the items may not necessarily be attached together.

[0035] The word "exemplary" is used exclusively herein to mean "serving as an example, instance, or illustration." Any embodiment described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments.

[0036] While the various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.

[0037] Referring now to **FIG. 1** of the present disclosure, an endotracheal tube assembly **10** is shown in a profile view. The endotracheal tube assembly **10** is capable of insertion into a patient's trachea to ventilate, to maintain patency of the patient's airway, and to deliver therapeutic electromagnetic radiation (EMR) to the patient.

[0038] **FIGS. 1 and 2** illustrate that the therapeutic endotracheal tube assembly **10** comprises an endotracheal tube **12** and an EMR delivery system **13** having a lumen **14** defined by a tube wall **16** and a ventilator collar **18**. The endotracheal tube **12** has tube body **20** with an upper tube portion **21** having a proximate end **22** and a lower tube portion **23** having a forward end **24** for insertion into the patient's trachea. The proximate end **22** of the upper tube portion **21** of the tube body **20** is coupled to the ventilator collar **18** in any suitable manner. Further, the

endotracheal tube **12** typically has an inflatable cuff **26** surrounding the tube wall **16** proximate the forward end **24**. The lumen **14** of the endotracheal tube **12** is used principally to pass ventilating gas from the ventilator (not shown) to the patient's lungs. However, the lumen **14** may be used as conduit for the passage of medical instruments of various kinds, including the EMR delivery system **13** of this disclosure. Also, it should be understood that a secondary lumen (not shown in **FIGS. 1 and 2**, but see **FIG. 13** for examples of secondary lumens) may be used as a conduit for the insertable portions of the EMR delivery system **13.**

[0039] In the exemplary embodiment of **FIG. 1**, the endotracheal tube **12** has two separate side ports **28**, a cuff inflation conduit **30** and an optical conduit **32**. The cuff inflation conduit **30** has a cuff inflation fitting **34** through which an inflation fluid is injected to inflate the inflatable cuff **26** to seal the trachea or removed to deflate the inflatable cuff **26** so that the endotracheal tube **12** may be removed from the patient's trachea. The optical conduit **32** receives the EMR delivery system **13** as will be described more fully below.

[0040] The exemplary embodiment of **FIG. 2** differs from the embodiment in **FIG. 1** in that the endotracheal tube **12** has a single, combined side port **28** because the cuff inflation conduit **30** ports into the optical conduit **32**. Although there are endotracheal tubes 12 that have two side ports 28, to best accommodate the EMR delivery system **13**, the exemplary embodiments of **FIGS. 1 and 2** would most likely be custom made for optimum compatibility with the EMR delivery system **13**. Nevertheless, if one of the side ports **28** in an off-the-self, multiple side port endotracheal tube **12** is suitably compatible with the EMR delivery system **13**, then such an endotracheal tube **12** need not be custom made.

[0041] The EMR delivery system **13** comprises an EMR source **36** for emitting non-ultraviolet, therapeutic EMR having intensity sufficient to activate desired therapeutic properties within the patient, an EMR conduction line **37** (shown in phantom lines) conducive to the propagation of EMR from the EMR source **36** along the endotracheal tube **12**, and an EMR coupling **38** to connect the EMR source **36** to a coupling end **39** of the EMR conduction line **37**. Such desired therapeutic properties within the patient may include stimulating healthy cell growth or sterilizing one or more target organisms or infectious agents.

[0042] The EMR source **36** may comprise an optical element (not shown) such as light emitting diodes, lasers, filtered fluorescents, filtered incandescents, and any combination thereof. The EMR source **36** may provide non-ultraviolet, sterilizing EMR at one or more wavelengths in the range of approximately 380 nm to approximately 900 nm. In order to provide sufficient inactivation of infectious agents, each EMR wavelength should be of a narrow spectrum centered about a wavelength that has demonstrated sterilization when applied at an intensity sufficient to inactivate one or more infectious agents. Several exemplary wavelengths have demonstrated desirable sterilization, including those wavelengths centered about: 400 nm, 405 nm, 415 nm, 430 nm, 440 nm, 455 nm, 470 nm, 475 nm, 660 nm, and 808 nm.

[0043] Of particular interest to this endotracheal tube assembly **10** is the use of light between 380 and 900 nm wavelengths. Additionally, the intensity and power of the light emitted is particularly suitable for the inactivation of infectious agents, thus a range of fluency covering 0.1 J/cm^2 to 1 kJ/cm^2 and a range of powers from 0.005 mW to 1 W, and power density range covering 1 mW/cm^2 and 1 W/cm^2 are of interest for these device assemblies and methods.

[0044] Also of interest to this endotracheal tube assembly **10** is the use of use of different wavelengths between 532 and 1064 nm for stimulating tissue healing properties. Exemplary wavelengths have demonstrated desirable tissue healing properties, including those wavelengths centered about 633 nm, 808 nm, and 830 nm. Doses ranging from 0.09 to 90 J/cm^2 have been demonstrated to be effective, with the predominating values from 1 to 5 J/cm^2. However, doses 150 J/cm^2 are of particular interest for the applications contemplated by this disclosure.

[0045] For each exemplary embodiment described herein, the endotracheal tube assembly **10** and method for disinfection could be utilized in an adjustable or predetermined duty cycle. If treatments began immediately after sterile procedure was initiated, device related infections may be inhibited. This includes device related biofilm growth.

[0046] A treatment may include at least one wavelength of therapeutic EMR that acts as a predominant wavelength selected to sterilize one or more target organisms and selected from the group of wavelengths centered about 400 nm, 405 nm, 415 nm, 430 nm, 440 nm, 455 nm, 470 nm, 475 nm, 660 nm, and 808 nm. Another treatment may include alternating the predominant wavelength between a first predominant wavelength and a second predominant wavelength (differing from the first predominant wavelength) in a selected treatment pattern. Further,

sterilizing EMR and EMR that stimulates healthy cell growth may be transmitted simultaneously in tandem or alternatively.

[0047] The EMR conduction line **37** has the coupling end **39** and a distal end **41** and may be insertable into the endotracheal tube **12** to deliver non-ultraviolet, therapeutic EMR within the patient at sufficient intensity to activate desired therapeutic properties. The EMR conduction line **37** may comprise one or more optical features such as a reflective surface, an optically transmissible material, a lens, a fiber optic filament, a gradient modification, light emitting portions, opaque portions, or any combination thereof. The EMR conduction line **37** may also comprise plastic, silica, or other polymeric optical fiber capable of transmission and dispersion of light over a given distance.

[0048] Also, at least a portion of the endotracheal tube **12** may be optically clear or translucent. These portions of clearness or translucency permit the EMR emitted from the EMR conduction line **37** to deliver therapeutic EMR to the inside of the tube wall **16** and to body tissue external to the tube wall **16** and proximate the clear or translucent portions. In most cases, the endotracheal tube **12** will be an off-the-shelf (rather than custom made) item and the entire length of the endotracheal tube **12** will be clear or translucent. However, it should be understood that custom made endotracheal tubes **12** may have portions that are not clear or translucent so not to permit the emission of the EMR from the endotracheal tubes **12** at those opaque portions.

[0049] The EMR conduction line **37** may comprise at least one optical feature selected from a group of optical features such as a reflective surface, an optically transmissible material, a lens, a fiber optic filament, and any combination thereof. It also may be capable of transmitting more than one wavelength or intensity EMR. Multiple wavelengths may be transmitted simultaneously, one after another or in tandem, or a combination thereof (for example, one constantly on and the other wavelength pulsed). Multiple intensities may be transmitted through the same element simultaneously. Alternating patterns of light treatments may also be transmitted.

[0050] The optical conduit **32** may be incorporated onto, into, or through the endotracheal tube body **12** at optical joinder site **40** and the cuff inflation conduit **30** may be incorporated onto, into, or through the endotracheal tube body **20** at inflation joinder site **42**, as shown in **FIG. 1**. The single, combined side port **28** of **FIG. 2** may be incorporated onto, into, or through the

endotracheal tube body **12** at combined joinder site **44** and the cuff inflation conduit **30** may be incorporated onto, into, or through the optical conduit **32** at a combining site **46**. Together, the cuff inflation conduit **30** and the optical conduit **32** form a combined conduit **48.**

[0051] The ventilator collar **18** depicted in **FIGS 1-5** represents a typical ventilator collar **18** known in the art. Of course, other types of connectors may be used to connect to a ventilator (not shown), and the ventilator collar **18** could be modified to accommodate a suitable connection of the endotracheal tube **12** to a ventilator without departing from the spirit of the invention. As depicted, the ventilator collar **18** comprises a connection sleeve **49** that secures the endotracheal tube **12** to the ventilator collar **18**, a stop flange **50** to arrest over-engagement, and an engagement cylinder **51**. Depending on the diameter of the ventilator connector (not shown), the ventilator may be coupled to the engagement cylinder **51** in either a snug male or female engagement.

[0052] **FIG. 3** illustrates another exemplary embodiment that differs from the two previously described. With this embodiment, the endotracheal tube **12** has one or more embedded, partially embedded, or internally channeled EMR conduction lines **37** (not visible in **FIG. 3**, but described in more detail regarding **FIGS. 9-13** below) and a single side port **28** for the cuff inflating conduit **30**. The EMR source **36** has an EMR directing ring **52** disposed within a cylindrical aperture **54**. The ventilator collar **18** and the cylindrical aperture **54** share a centerline **56** when the cylindrical aperture aligns for engagement with the engagement cylinder **51** of the ventilator collar **18**. When the engagement cylinder **51** engages the cylindrical aperture **54** in male/female engagement, the EMR directing ring **52** communicates with the one or more embedded, partially embedded, or internally channeled EMR conduction lines **37** enable the propagation of EMR down the endotracheal tube **12**. The communication of EMR from the EMR directing ring **52** to the EMR conducting lines **37** may be accomplished in any of a number of ways known to those skilled in the art, such as by direct contact of exposed ends of the EMR conducting lines **37** to the EMR directing ring **52** or through one or more collimating lenses or reflective mirrors (not shown). This configuration allows the EMR source **36** to be effectively coupled to all or part of the engagement cylinder **51** so that therapeutic EMR may be delivered into a patient's body without interfering with the coupling to the ventilator.

[0053] **FIGS. 4 and 5** depict first an exploded view of an exemplary embodiment of a therapeutic endotracheal tube assembly **10** (**FIG. 4**) and then an engaged view (**FIG. 5**). **FIG. 15** is a perspective view of the therapeutic endotracheal tube assembly **10** in an engaged configuration. With this exemplary embodiment, an existing, off-the-shelf endotracheal tube **12** may be retrofitted with an endotracheal adapter **68** that converts the existing endotracheal tube **12** into a therapeutic endotracheal tube assembly **10** fully capable of delivering therapeutic EMR into a patient's body without interfering with the coupling to the ventilator. The endotracheal adapter **68** is disposed intermediate of the ventilator collar **18** and the ventilator.

[0054] The endotracheal adapter **68** of **FIGS 4-7** has an adapter body **69**, an EMR port **70**, a ventilator fitting end **71** corresponding in configuration to the engagement cylinder **51** of the ventilator collar **18**, an engagement end **72** configured to engage the engagement cylinder **51** in male/female engagement, an adapter stop flange **74** for arresting over-engagement with the ventilator, and a ventilation channel **75** through which ventilation gas may travel without meaningful interference. The ventilation channel **75** of the port adapter **68** may accommodate passage of one or more of a diagnostic probe, a therapeutic tool, an additional energy source, an optical device, a surgical instrument, and a monitor into the endotracheal tube **12.**

[0055] The EMR port **70** may have either an optical conduit **32** (as shown) or may receive the EMR conduction line **37** directly so long as the port is adequately sealed so that the ventilation operation will not be compromised. The form of seal may be any suitable seal known by those in the art, such as a rubber diaphragm that may be penetrated by the EMR conduction line **37** or O-rings positioned within the EMR port **70**, or the like.

[0056] The endotracheal adapter **68**, as retrofitted, enables the removable insertion of the EMR conduction line **37** to whatever depth within or through the tube body **20** is desired. The EMR conduction line **37** is shown in **FIG. 8** as being fully inserted within the tube body **20** where EMR illumination **76** is shown, by way of example, at the distal end **41** of the EMR conduction line **37**. Of course, it should be understood that therapeutic EMR may be delivered anywhere along the length of the tube body **20** provided the tube body **20** is clear or translucent at least at those portions of the tube body **20** where emitted therapeutic EMR is desired and the EMR conduction line **37** emits EMR of sufficient intensity directed (radially, obliquely,

longitudinally, from the distal end, and any combination thereof) through the tube body **20** to the desired location(s). The methods and apparatus for providing gradient modification and/or multiple emission portions for the EMR conduction line **37** are described in co-pending application entitled METHODS AND APPARATUS TO INACTIVATE INFECTIOUS AGENTS ON A CATHETER RESIDING IN A BODY CAVITY, U.S. Application Serial No. 13/801,750, filed March 13, 2013.

[0057] By way of example, **FIG. 6** shows the EMR conduction line **37** disposed directly within the EMR port **70** so that the EMR conduction line **37** may be inserted unobstructed into the ventilation channel **75** and then into the lumen **14** of the tube body **20** of the endotracheal tube **12** and may be subsequently removed.

[0058] Referring now to **FIGS. 9-13** of the present disclosure, depicted are cross-sectional views of various exemplary configurations of the endotracheal tube body **20**. The section taken is transverse to a longitudinal axis of the endotracheal tube body **20** at any point (other than at the balloon cuff **26**) along the axis downstream of the most downstream joinder site **40**, **42**, **44**. The cross-sectional views show a portion of the exemplary endotracheal tube bodies **20** sometimes identified herein as a distal endotracheal tube having a tube wall **16**, bounded by an internal surface **60** and an external surface **62**, encompassing the lumen **14**, previously identified.

[0059] **FIG. 9** illustrates one such configuration, wherein one or more distal optical conduits **64A-C** are embedded in the endotracheal tube wall **16** between the internal surface **60** and the external surface **62**. This configuration occurs distal to the site where the external optical conduit **32** ports into the endotracheal tube body **20**. An embedded cuff inflation conduit **58** is the downstream extension of the cuff inflation conduit **30** and is located along the wall **16** of the endotracheal tube body **20** between the inflation joinder site **42** and the inflatable cuff **26**.

[0060] Referring now to **FIG. 10**, a cross-sectional view illustrating another such configuration shows multiple distal optical conduits **64A-I** and the embedded cuff inflation conduit **58** embedded in the endotracheal tube wall **16**.

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[0061] In the cross-sectional view of **FIG. 11**, another exemplary configuration is depicted as a variation of the orientations and size of the distal optical conduits **64A-D** in the endotracheal tube wall **16**.

[0062] In **FIG. 12**, a cross-sectional view illustrates another exemplary configuration, wherein one or more distal optical conduits **64A-F** may be located along the internal surface **60** of the endotracheal tube wall **16**. As shown, they may be partially embedded within the endotracheal tube wall **16**.

[0063] Referring now to **FIG. 13**, a cross-sectional view illustrates yet another exemplary configuration, wherein one or more distal optical conduits **64A-D** may be located along the internal surface **60** of the endotracheal tube wall **56**. Differing from **FIG. 9**, the distal optical conduits **64A-D** are not embedded in the internal surface **60** of the endotracheal tube wall **16**, but are associated with the internal surface **60**, but may be enclosed within one or more optical conduit channels **66** that serve as secondary lumens to the main lumen **14**.

[0064] In another exemplary embodiment, the EMR source **36** may also be incorporated into the ventilator itself, using the ventilator tubing as a conduit for passing the optical conduit **32** to the endotracheal tube body **20**. The ventilator connection on the proximal end **22** of the endotracheal tube body **20** could then serve as a combined ventilator and optical conduit coupling apparatus. These connections could also be individual at the point of coupling with the endotracheal tube body **20**.

[0065] In another embodiment, EMR is transmitted directly down the endotracheal tube wall **16** using the tube wall **16** as an optical conduit. This may be done in conjunction with any of the other EMR source **36** configurations specifically mentioned above or that would be understood by those skilled in the art armed with this disclosure.

[0066] **FIG. 14** is a profile, sectional view illustrating an exemplary embodiment of a port adapter **68** having a tripartite configuration for connection to an endotracheal tube **12**, wherein the tripartite port adapter **68** accommodates the connection of various-sized ventilator connectors in either male or female engagement and also accommodates the insertion of an EMR conduction line **37** of an EMR delivery system **13** into the endotracheal tube **12**. The tripartite port adapter **68** comprises ventilator collar **18**, an EMR port **70**, engagement end **72**, and a

secondary port **78**. The ventilator collar **18**, EMR port 70, engagement end **72,** and secondary port **78** are angled from each other such that the multiple connections with ventilator, EMR delivery system **13**, endotracheal tube **12**, and any other type of device (a diagnostic probe, a therapeutic tool, an additional energy source, an optical device, a surgical instrument, a monitor, and the like) may be connected to the tripartite port adapter **68** without obstruction or interference.

[0067] The ventilator collar **18** has a first inner diameter **80** and a first outer diameter **82** that differs from the second inner diameter **84** and second outer diameter **86** of the secondary port **78** of the tripartite port adapter **68** so that the tripartite port adapter **68** can accommodate connection to ventilators having different-sized connectors. Of course, if any of the ventilator collar **18**, EMR port **70,** and secondary port **78** is not needed or is between uses, they may be capped so not to compromise ventilation of the patient.

[0068] As shown in **FIG. 14**, the tripartite port adapter **68** maybe retrofit between a ventilator and an endotracheal tube **12**. However, it should be understood that a custom-made endotracheal tube **12** may be made by affixing the tripartite port adapter **68** (as the ventilator collar **18**) directly to the tube body **20**. To affix the tripartite adapter **68** directly to the tube body **20**, any suitable coupling may be used, such as an adhesive, a pinch coupling, a male/female connection, or barbed inserted component, for example.

[0069] While specific embodiments and applications of the present disclosure have been illustrated and described, it is to be understood that the invention is not limited to the precise configuration and components disclosed as exemplary embodiments herein. Various modifications, changes, and variations which will be apparent to those skilled in the art may be made in the arrangement, operation, and details of the methods and systems of the present invention disclosed herein without departing from the spirit and scope of the invention.

The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. A therapeutic endotracheal tube assembly for insertion into a patient's trachea to ventilate, to maintain patency of the patient's airway, and to deliver therapeutic electromagnetic radiation (EMR) to the patient, the therapeutic endotracheal tube assembly comprising:

an endotracheal tube having:

a) a lumen defined by a tube wall, an upper tube portion having a proximate end, and a lower tube portion having a forward end for insertion into the patient's trachea, and

b) an inflatable cuff surrounding the tube wall proximate the forward end; and

an EMR delivery system comprising:

a) an EMR source for emitting non-ultraviolet, therapeutic EMR having intensity sufficient to activate desired therapeutic properties within the patient, the EMR source further comprises a range of fluency covering 0.1 J/cm^2 to 1 kJ/cm^2, and a range of powers from 0.005 mW to 1 W, and power density range covering 1 mW/cm^2 to 1 W/cm^2;

b) an EMR conduction line conducive to a propagation of EMR from the EMR source along the endotracheal tube, the EMR conduction line having a coupling end and a distal end and being insertable into the endotracheal tube to deliver non-ultraviolet, therapeutic EMR within the patient at sufficient intensity to activate desired therapeutic properties; and

c) a coupling to connect the EMR source to the coupling end of the EMR conduction line;

wherein:

the endotracheal tube further comprises a ventilator collar, the upper tube portion having a proximate end coupled to a ventilator collar; and

the therapeutic endotracheal tube assembly further comprises an endotracheal adapter disposed intermediate of the ventilator collar and the ventilator, the EMR conduction line is disposed directly within the EMR port so that the EMR conduction

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line is insertable into a ventilation channel and then into the lumen of the tube body of the endotracheal tube and may be subsequently removed.

2. An assembly as in claim 1, wherein at least a portion of the endotracheal tube is at least one of optically clear and translucent so that the therapeutic EMR emits from the EMR conduction line at least one of internally and externally to the endotracheal tube.

3. An assembly as in claim 1, wherein the EMR source comprises an optical element, the optical element being selected from a group of optical elements consisting of light emitting diodes, lasers, filtered fluorescents, filtered incandescents, and any combination thereof.

4. An assembly as in claim 1, wherein the endotracheal tube further comprising a receiving element for receiving the insertion of the EMR conduction line, the receiving element being selected from a group of receiving elements consisting of an embedded conduit embedded within the tube wall, a secondary internal lumen, a partially-embedded channel, and an exterior adjacent channel.

5. An assembly as in claim 1, wherein the therapeutic EMR is delivered at a predetermined duty cycle.

6. An assembly as in claim 1, wherein the therapeutic EMR has at least one wavelength, each wavelength being within the range from 380 nm to 900 nm.

7. An assembly as in claim 1, wherein the at least one wavelength of therapeutic EMR comprises a predominant wavelength selected to sterilize one or more target organisms and selected from a group of wavelengths consisting of wavelengths centered about 400 nm, 405 nm, 415 nm, 430 nm, 440 nm, 455 nm, 470 nm, 475 nm, 660 nm, and 808 nm.

8. An assembly as in claim 7, wherein the predominant wavelength alternates between a first predominant wavelength and a second predominant wavelength in a selected treatment pattern.

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9. An assembly as in claim 1, wherein the EMR conduction line is movable axially relative to the endotracheal tube.

10. An assembly as in claim 1, wherein the ventilator collar comprises a tripartite configuration having a first collar, a second collar, and an entry conduit, the first collar having a first cylindrical portion having a first interior diameter and a first exterior diameter that differs from a second interior diameter and a second exterior diameter of a second cylindrical portion of the second collar, the entry conduit for receiving a passage of the EMR conduction line into the endotracheal tube.

11. An assembly as in claim 1, wherein the EMR conduction line emits EMR from at least a portion of the EMR conduction line, emission of the EMR from the EMR conduction line being from a group of emissions consisting of radial, oblique, longitudinal, from the distal end, and any combination thereof.

12. An assembly as in claim 10, wherein the endotracheal adapter has an aperture through which at least one of a diagnostic probe, a therapeutic tool, an additional energy source, an optical device, a surgical instrument, and a monitor passes into the endotracheal tube.

13. An assembly as in claim 1, wherein the endotracheal adapter is removably attachable to the ventilator collar such that the EMR delivery system or EMR conduction system is retrofit to the endotracheal tube.

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1/11 FIG. 1

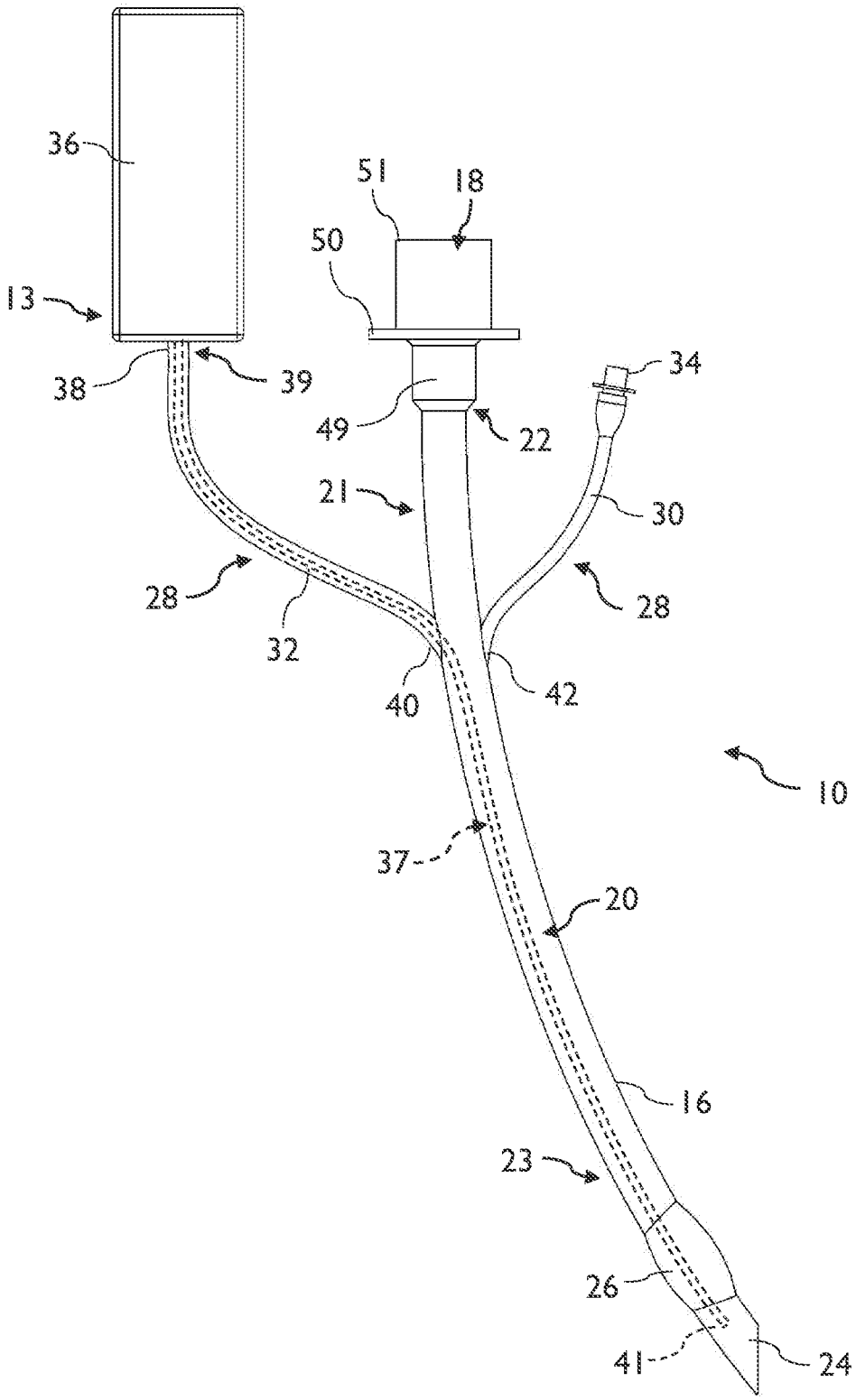
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FIG. 2

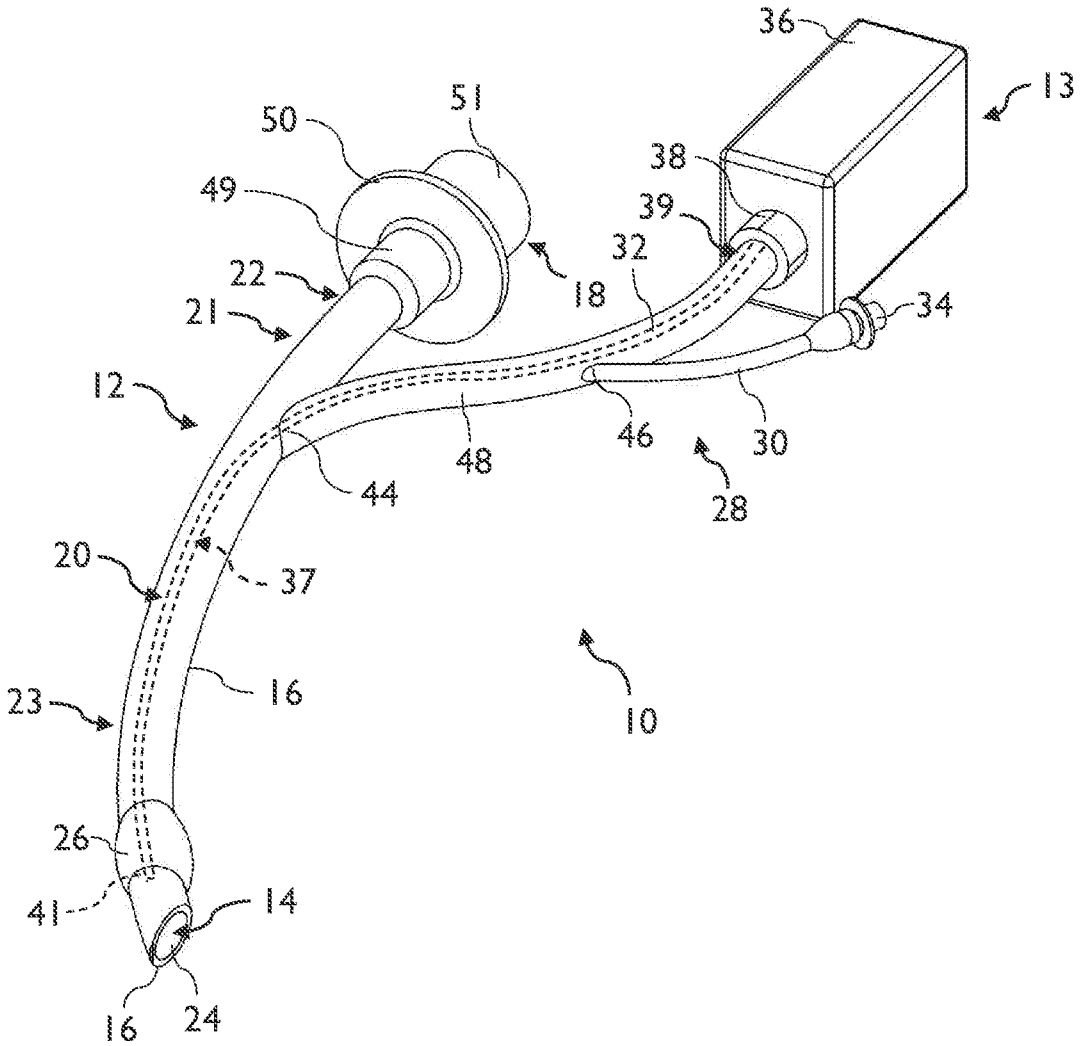
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FIG. 3

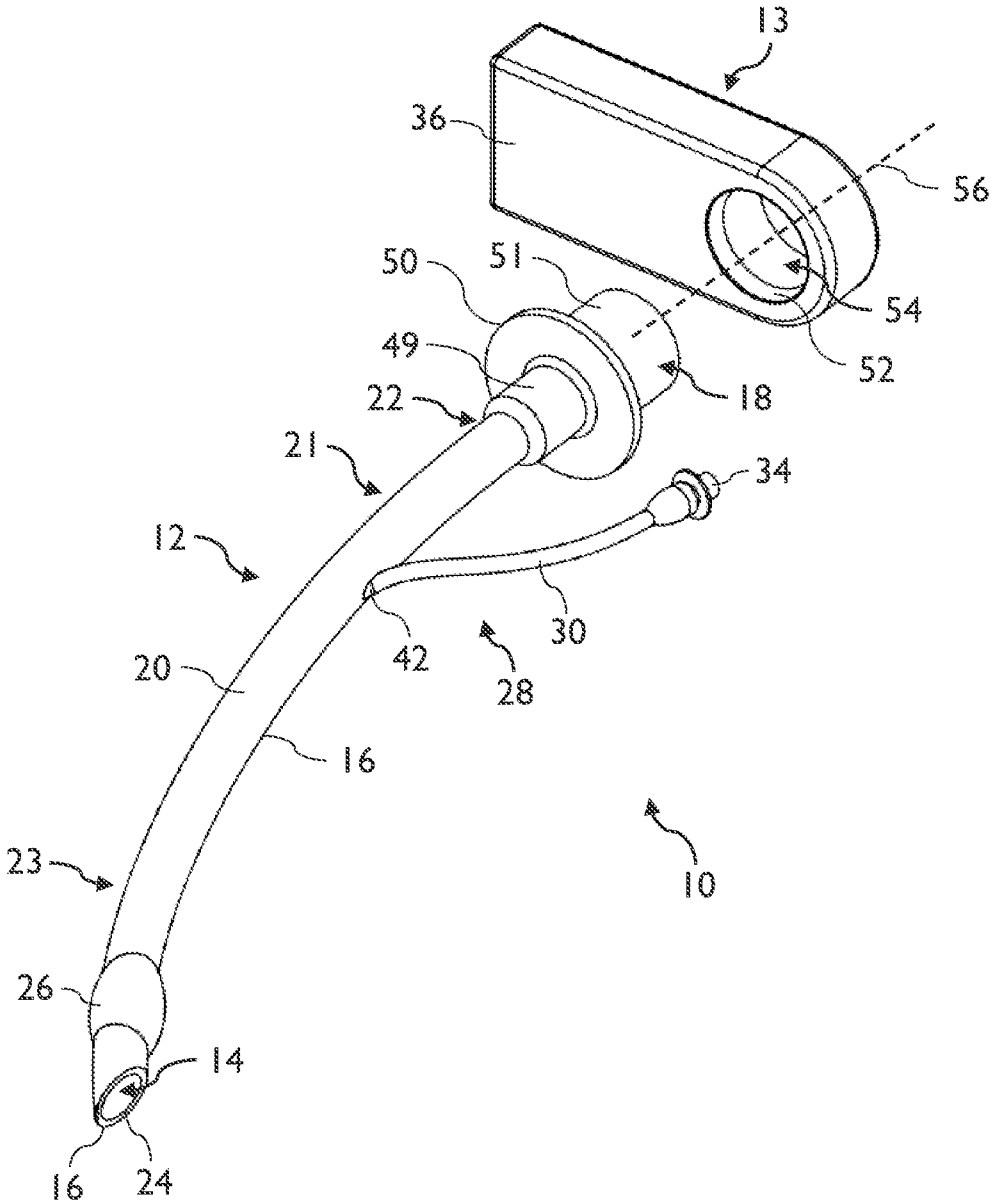

FIG. 4

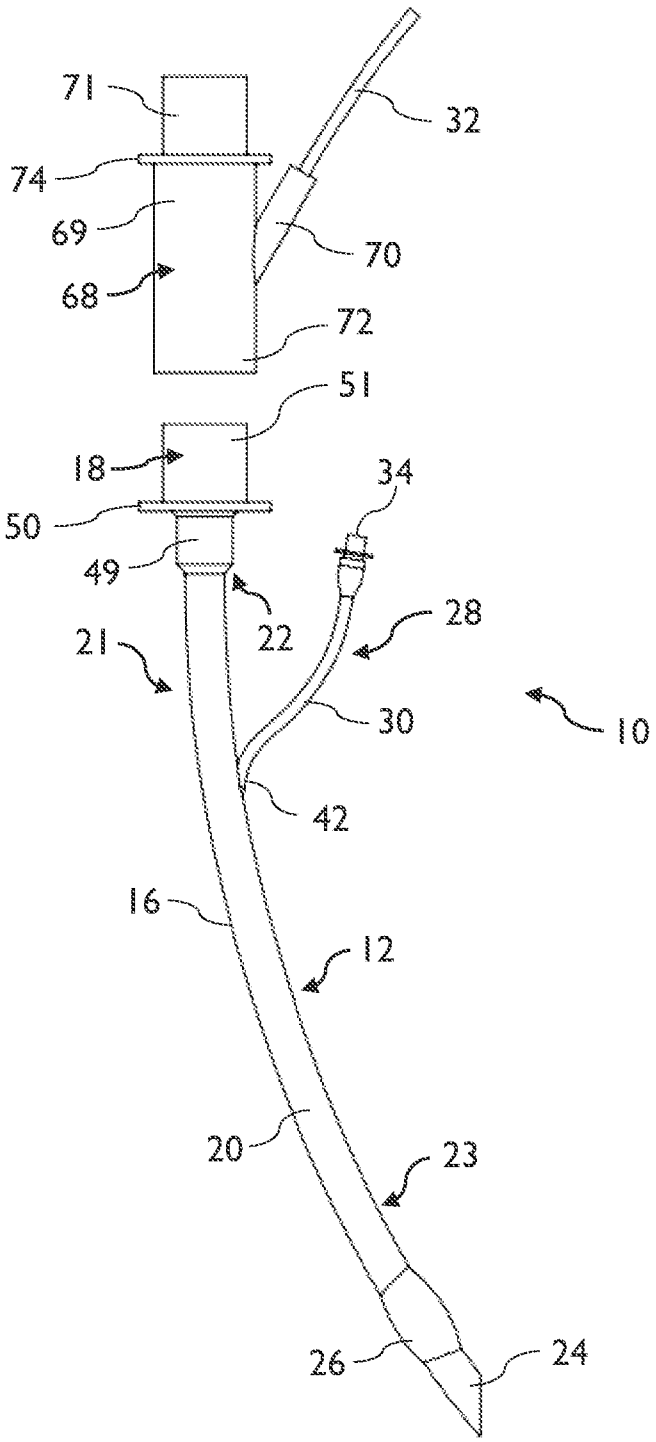

FIG. 5

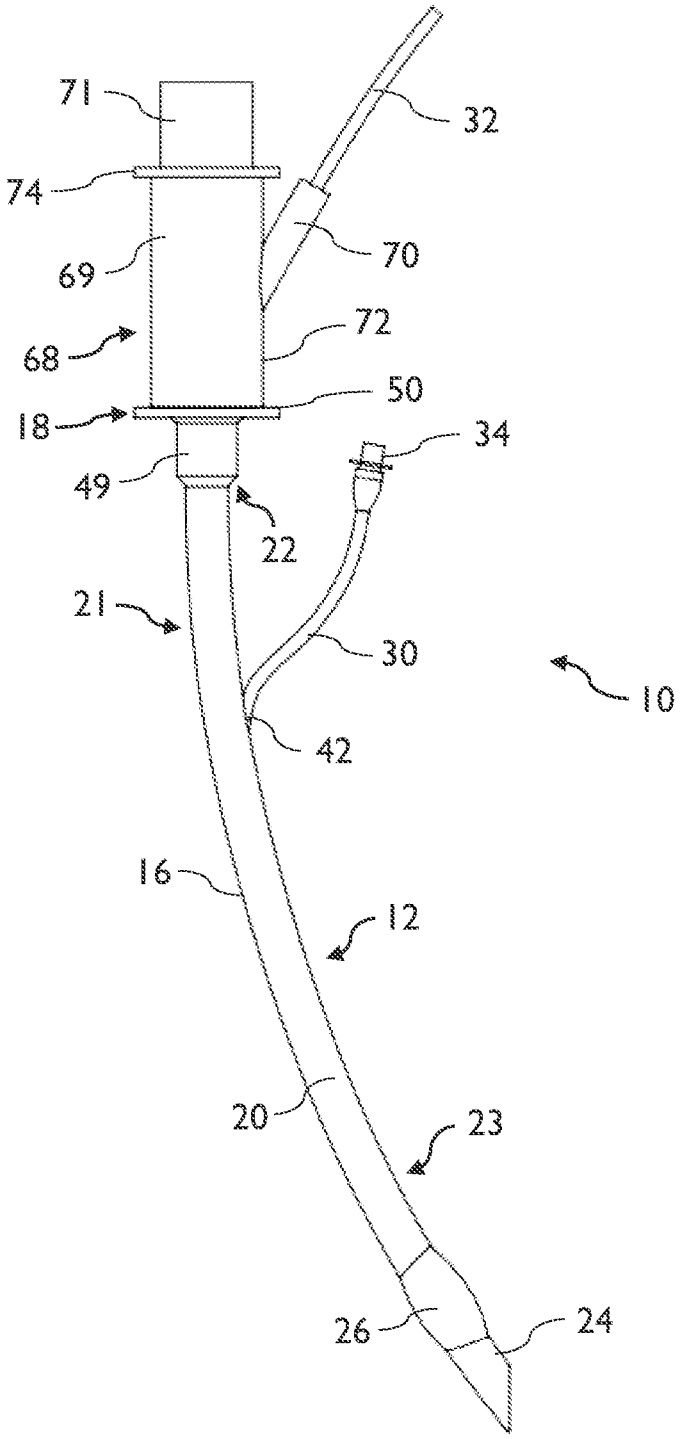

FIG. 6

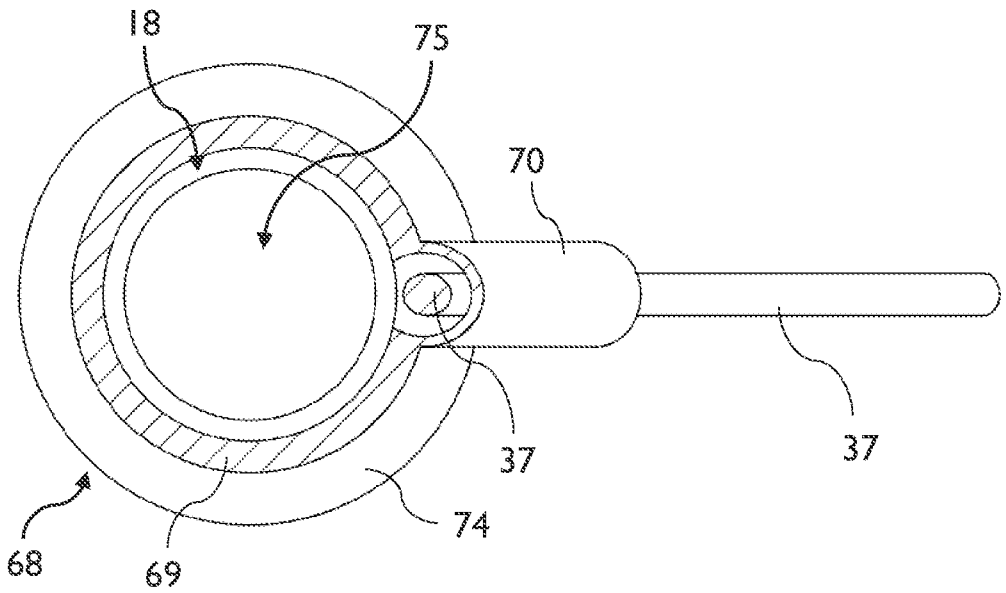

FIG. 7

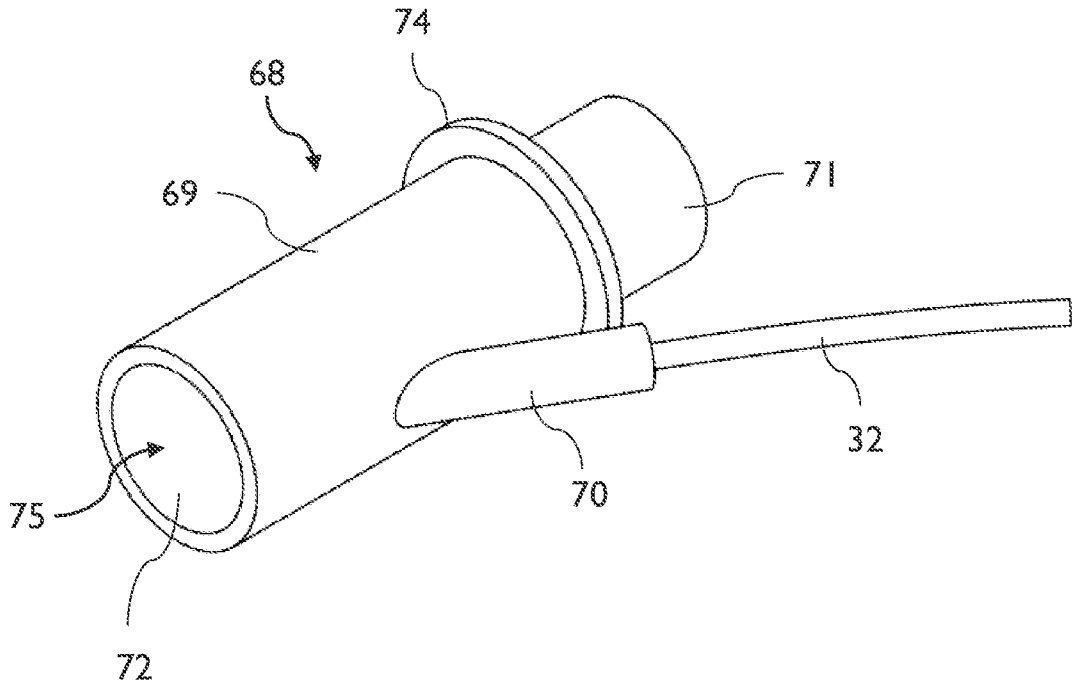

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FIG. 8

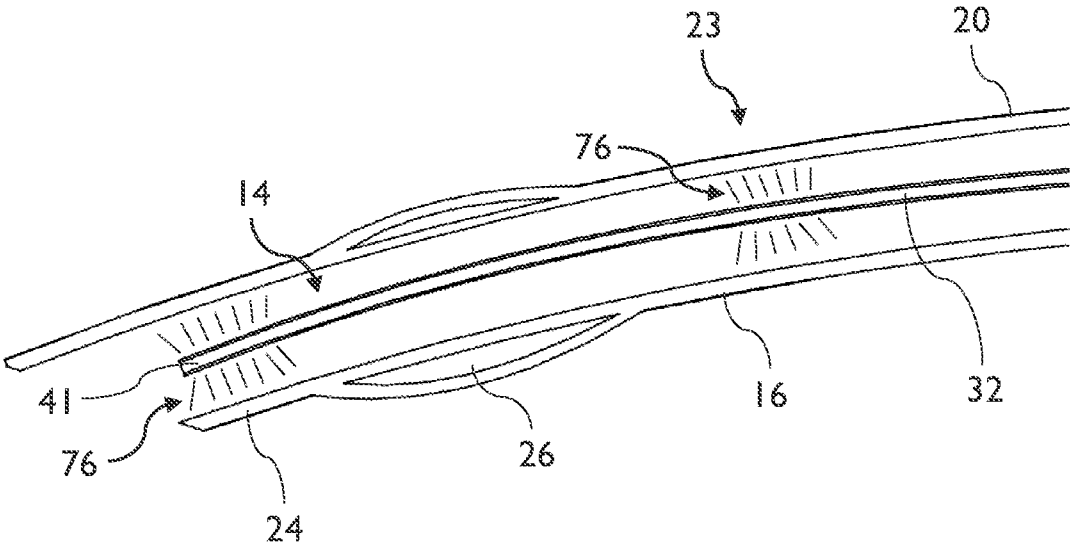

FIG. 9

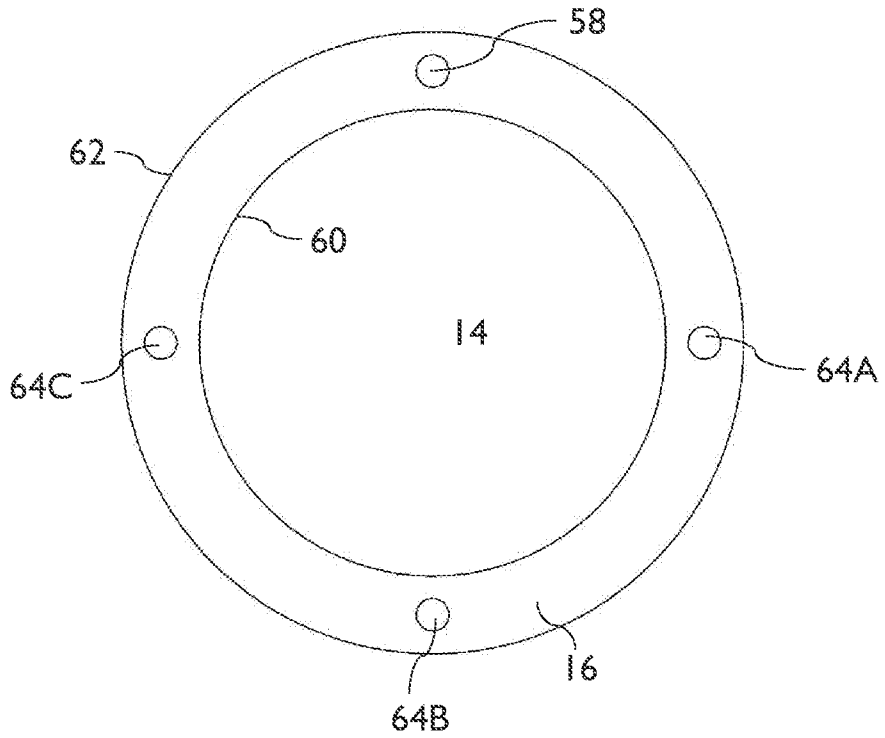
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FIG. 10

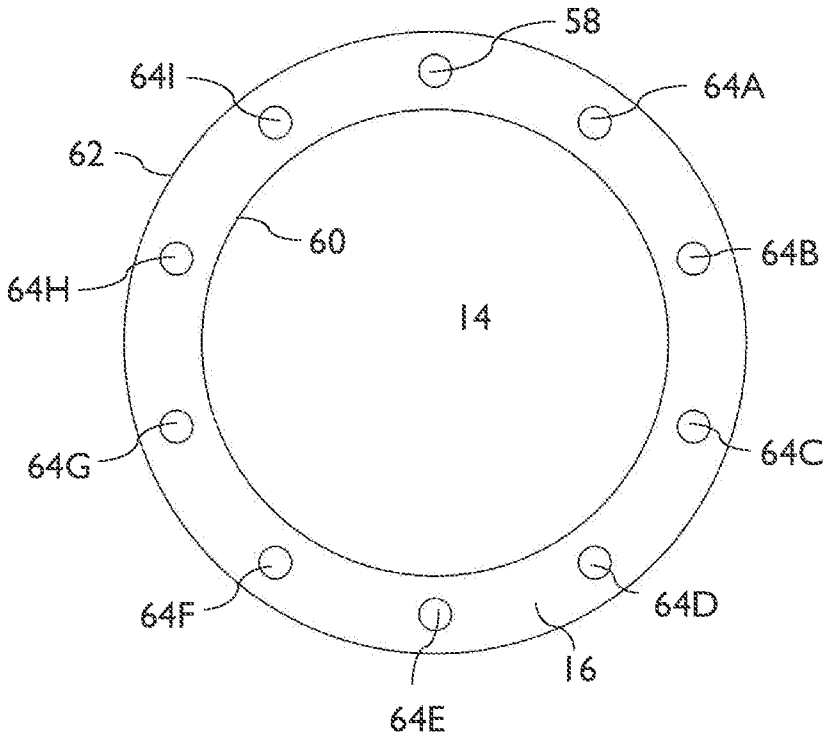
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FIG. 11

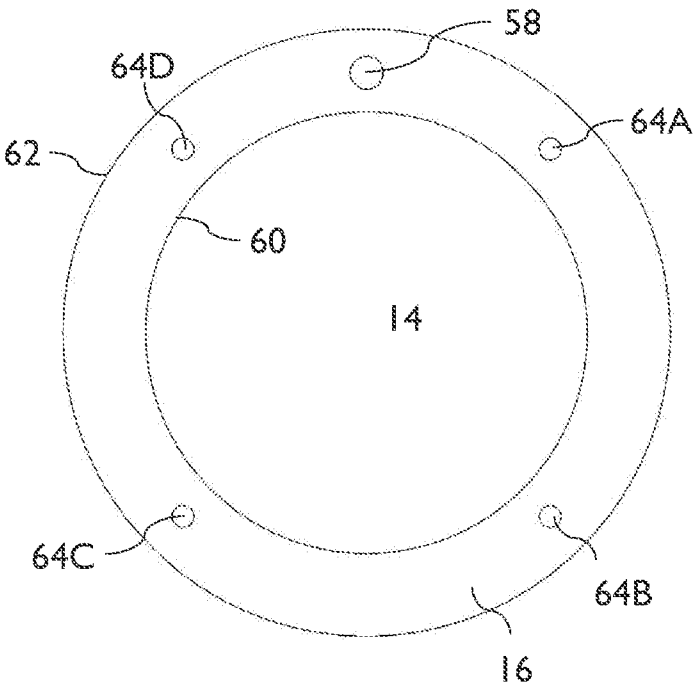
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FIG. 12

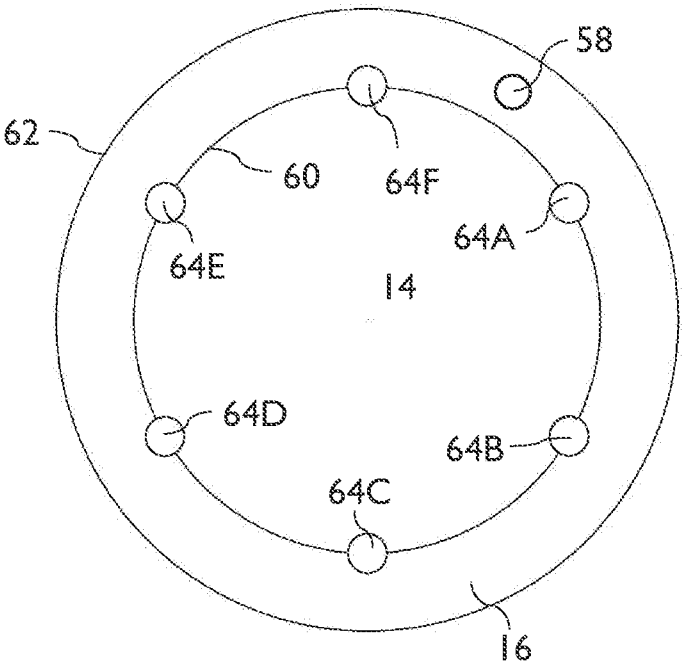
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FIG. 13

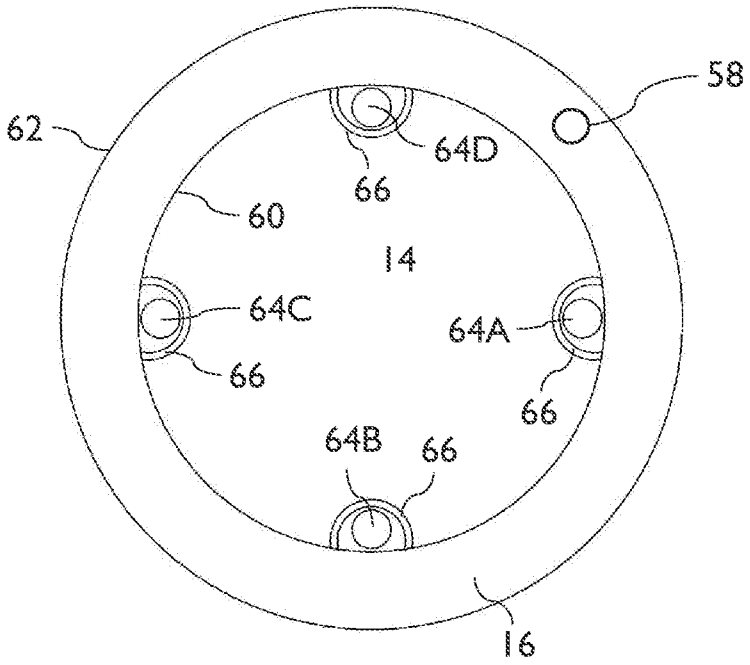
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FIG. 14

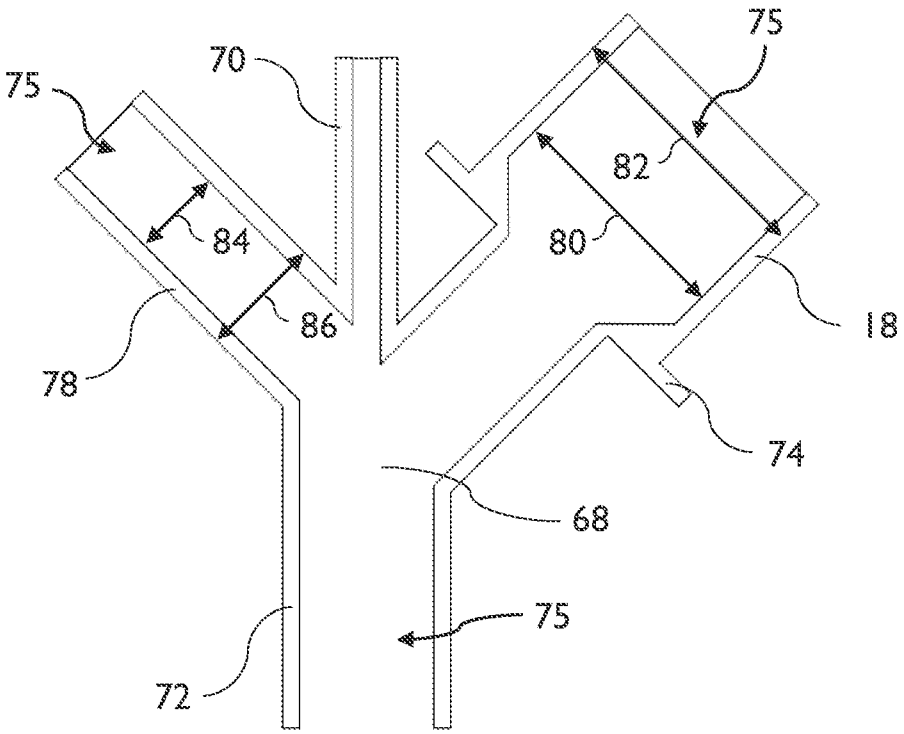
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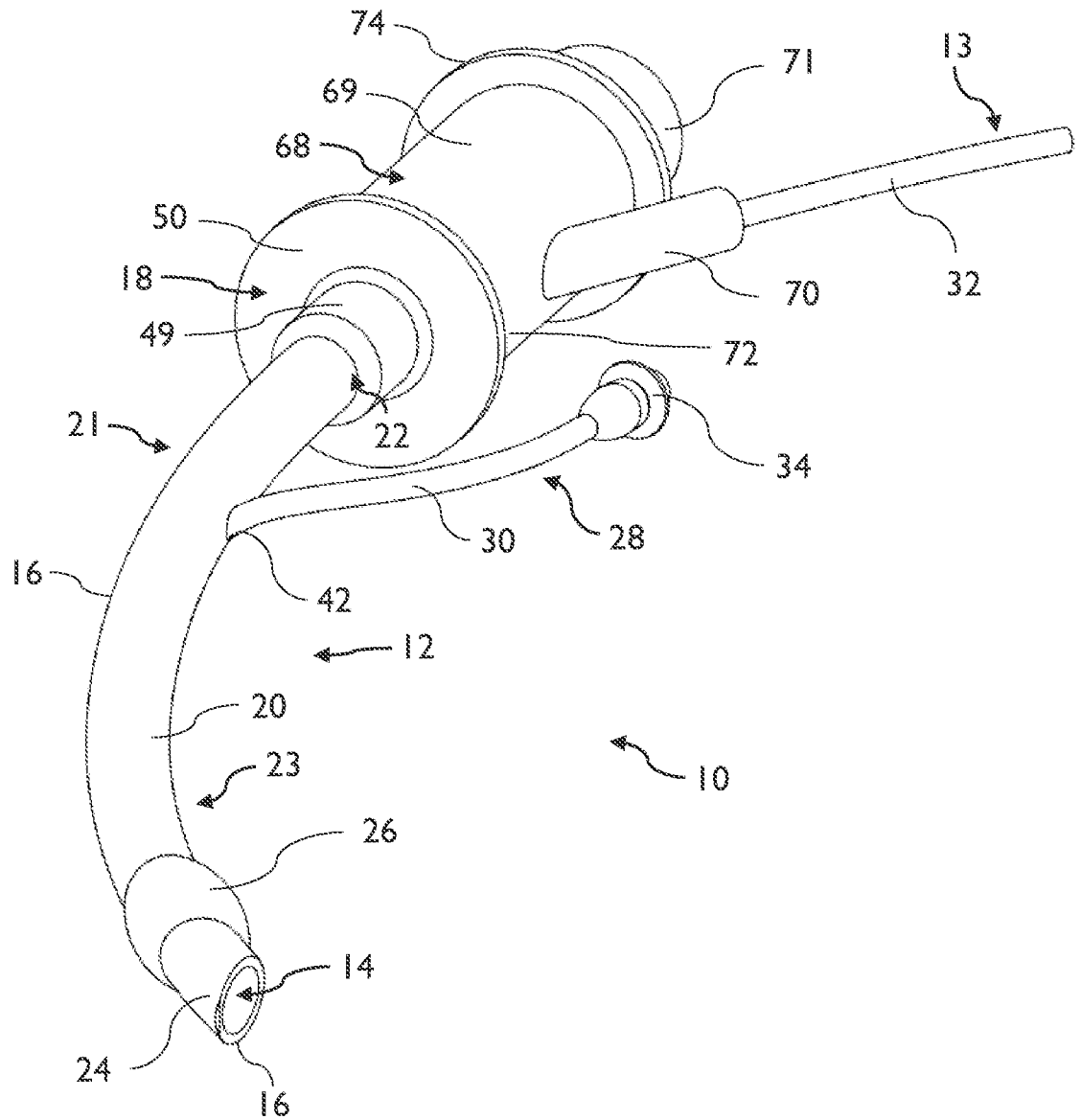
FIG. 15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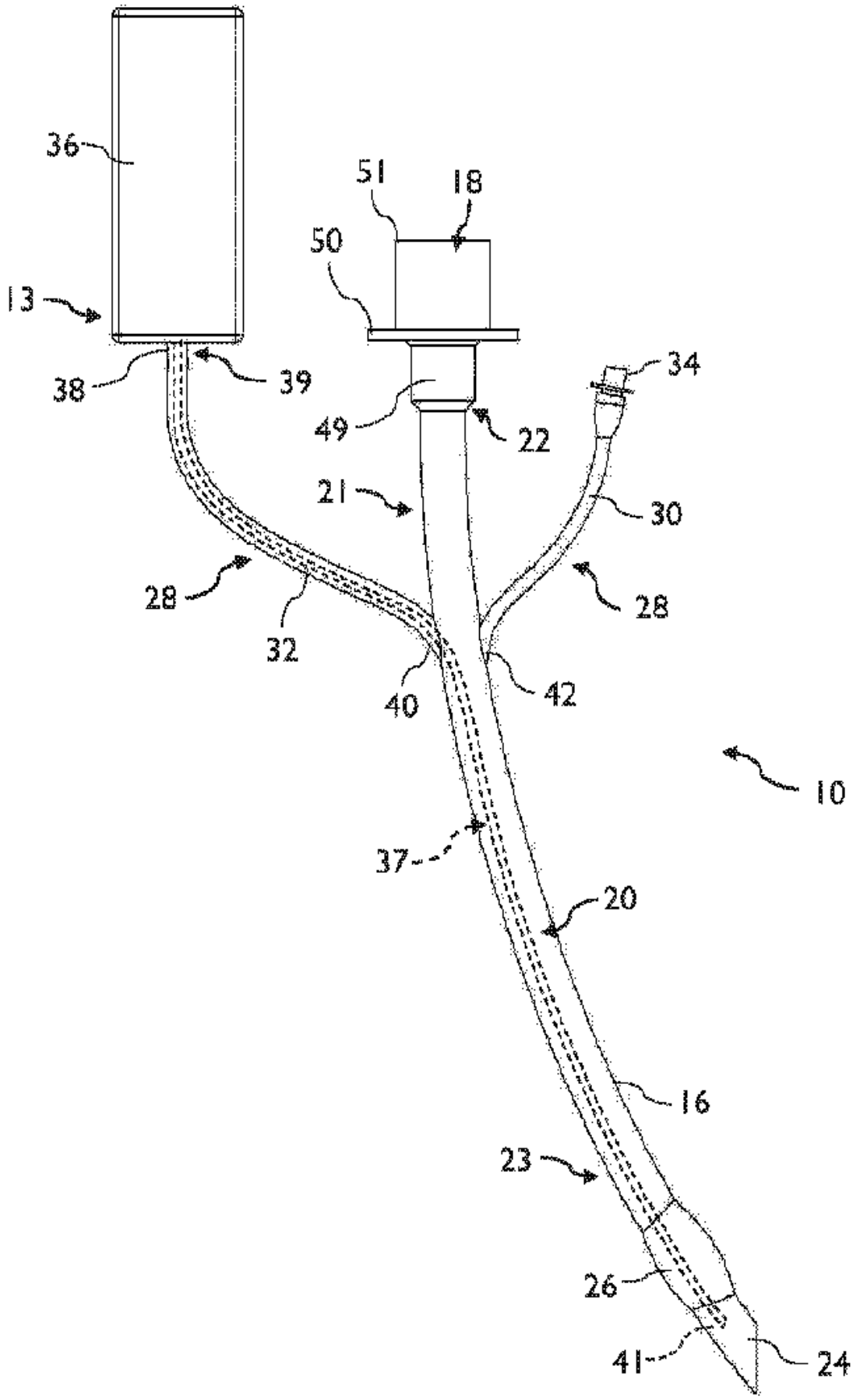
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