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Weaver et al.

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(54) **ORAL CANNULA**

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(51) **Int. Cl.**

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A61M 16/04	(2006.01)
A61M 16/06	(2006.01)
A61B 5/00	(2006.01)
A61B 5/097	(2006.01)
A61M 16/10	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 16/085*** (2014.02); ***A61B 5/0836*** (2013.01); ***A61B 5/097*** (2013.01); ***A61B 5/4839*** (2013.01); ***A61M 16/0463*** (2013.01); ***A61M 16/0486*** (2014.02); ***A61M 16/0666*** (2013.01); ***A61M 16/1005*** (2014.02); *A61M 16/0418* (2014.02); *A61M 16/0488* (2013.01); *A61M 2202/0007* (2013.01); *A61M 2202/0208* (2013.01); *A61M 2210/0625* (2013.01); *A61M 2230/432* (2013.01)

(58) **Field of Classification Search**

CPC A61M 16/085; A61M 16/0486; A61M 16/1005; A61M 16/0463; A61M 16/0666; A61M 16/0418; A61M 16/0488; A61B 5/0836; A61B 5/097

See application file for complete search history.

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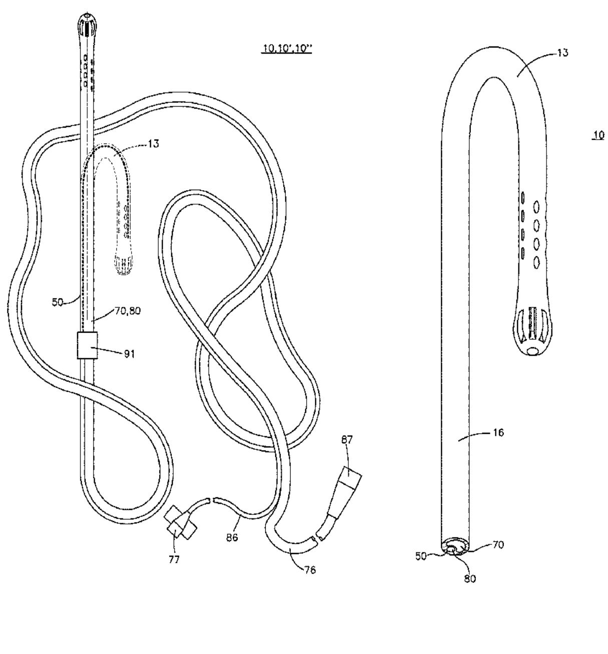
(57) **ABSTRACT**

An oral cannula for delivering oxygen and sampling end-tidal carbon dioxide includes an oxygen supply lumen having plural outlets and an end-tidal carbon dioxide (ETCO2) lumen having an inlet. The ETCO2 lumen and oxygen supply lumen form a unitary oral cannula such that the oxygen supply lumen outlet is spaced apart from the ETCO2 lumen inlet. The oral cannula is adapted for bending or has a bend such that the oral cannula is insertable and retainable in a patient's mouth.

25 Claims, 13 Drawing Sheets



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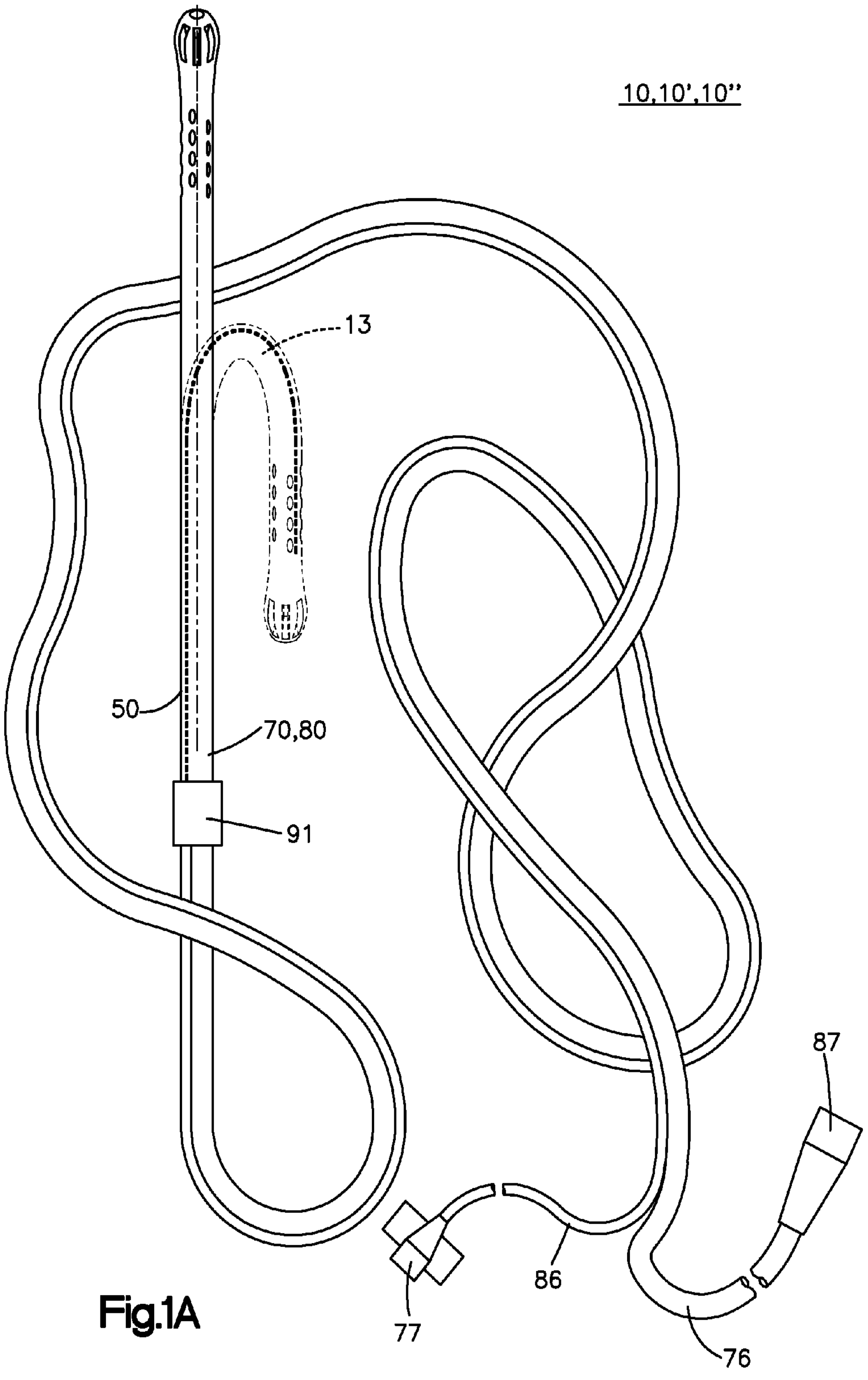

Fig.1A

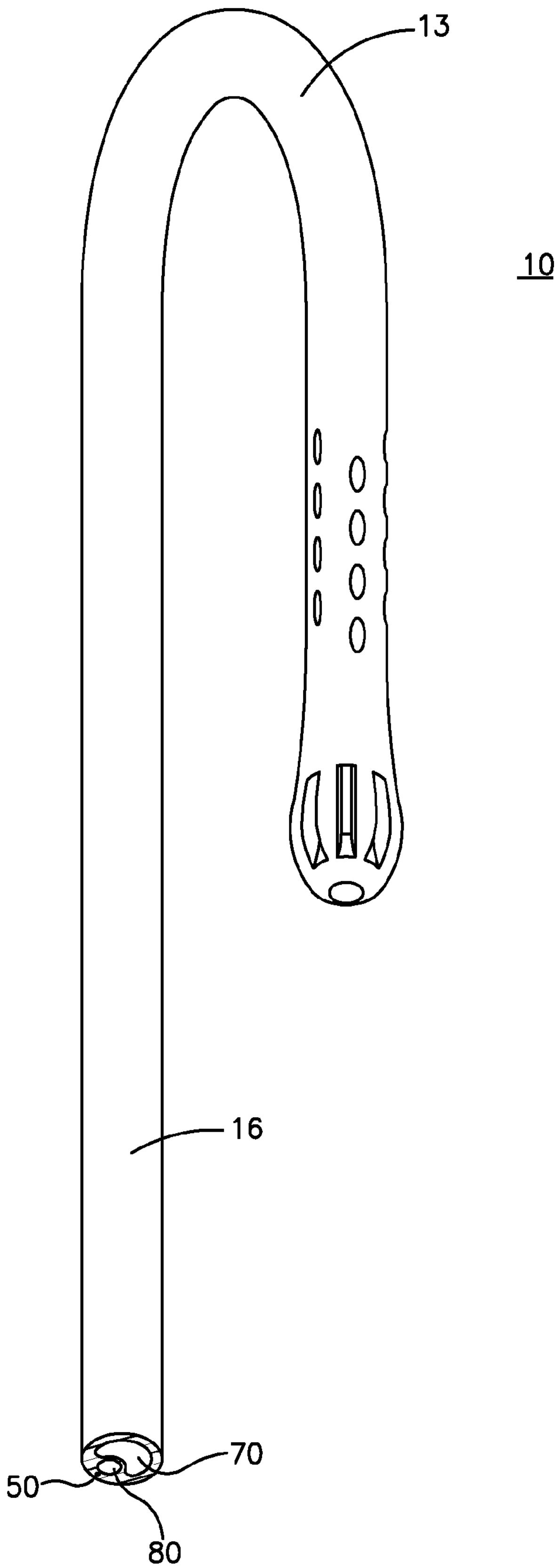

Fig.1B

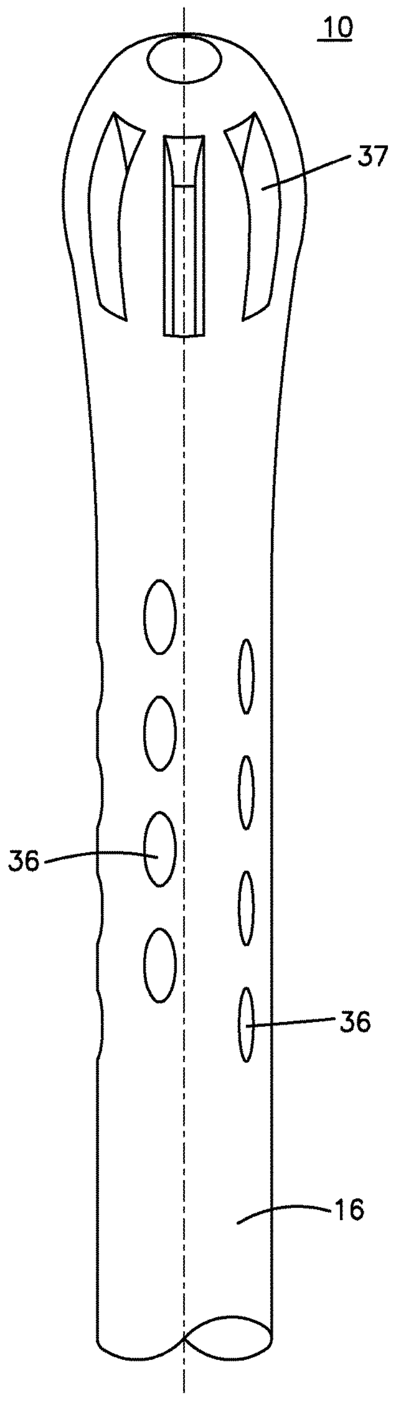

Fig.2A

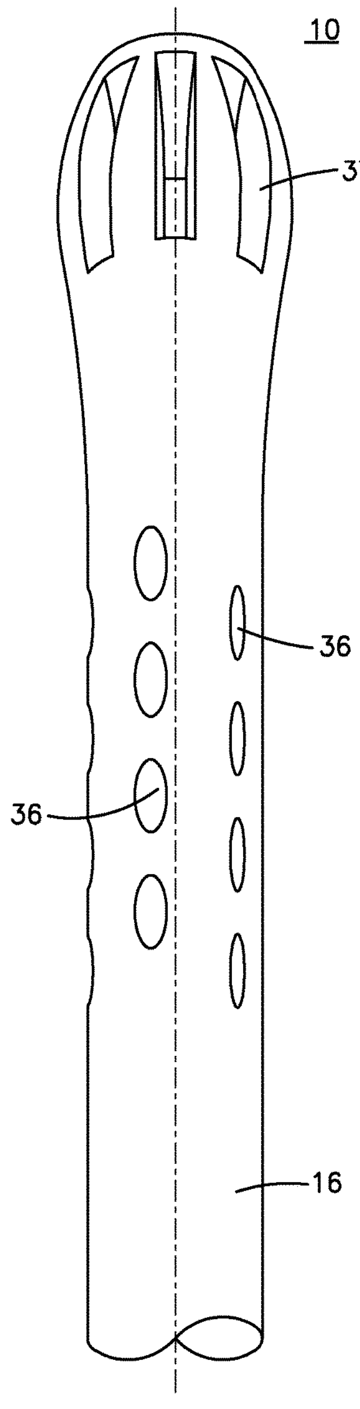

Fig.2B

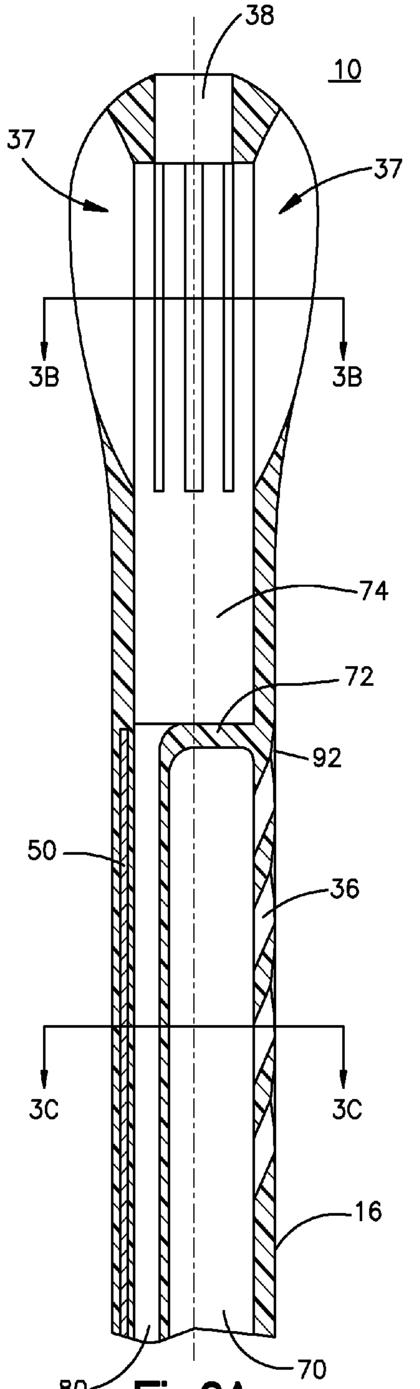

Fig.3A

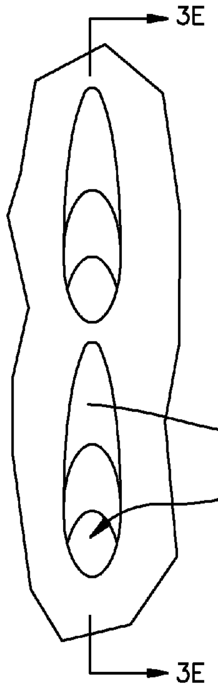

Fig.3D

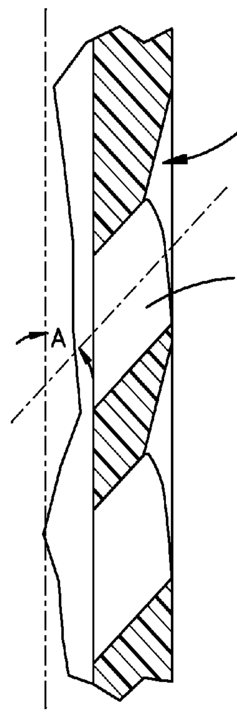

Fig.3E

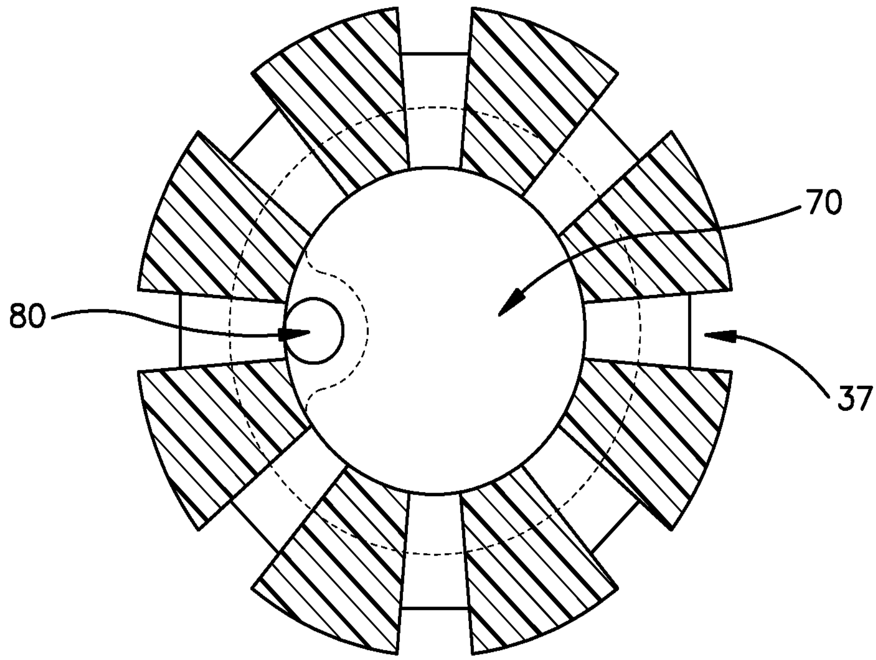

Fig.3B

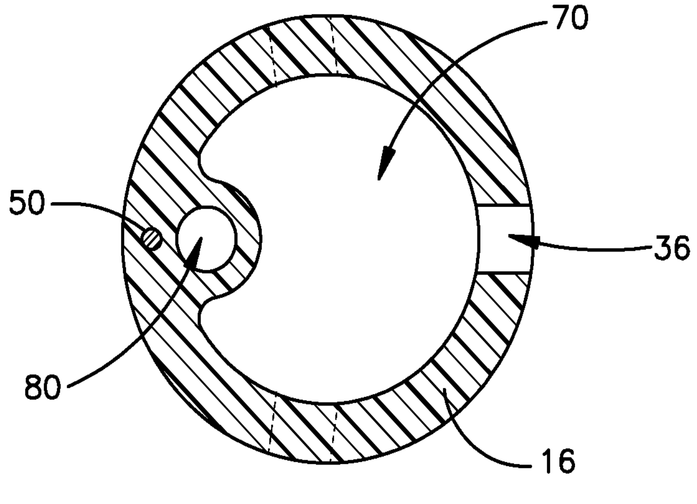

Fig.3C

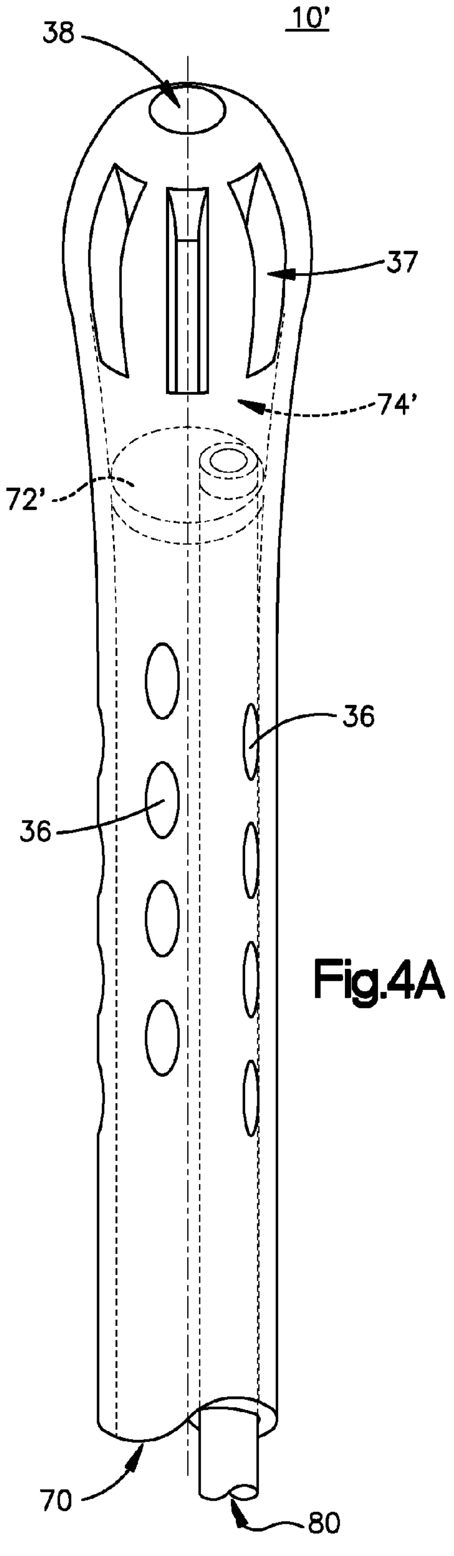

Fig.4A

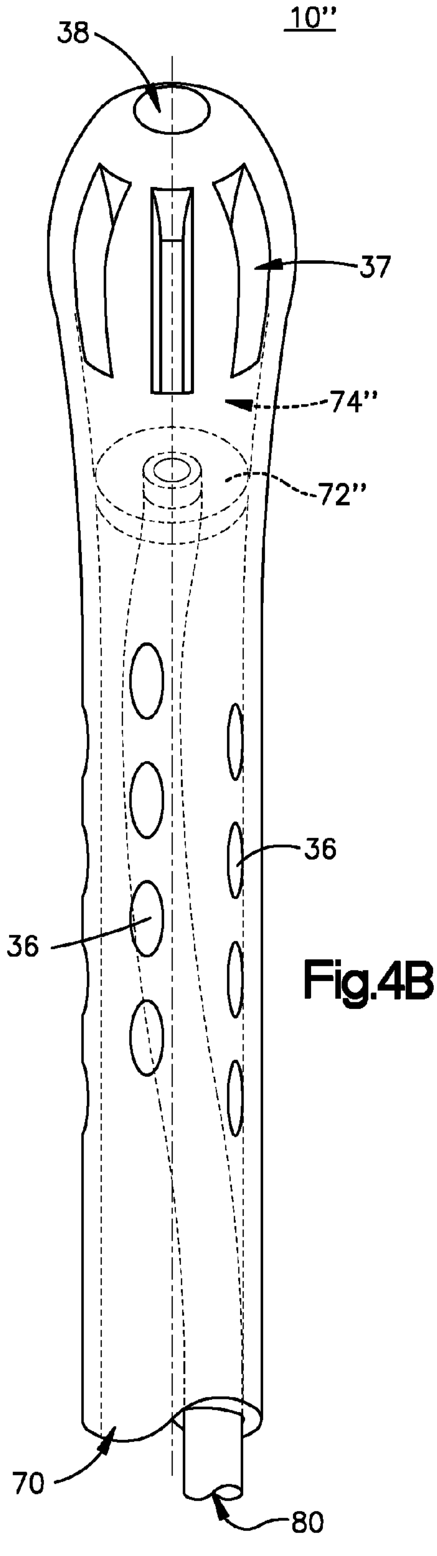

Fig.4B

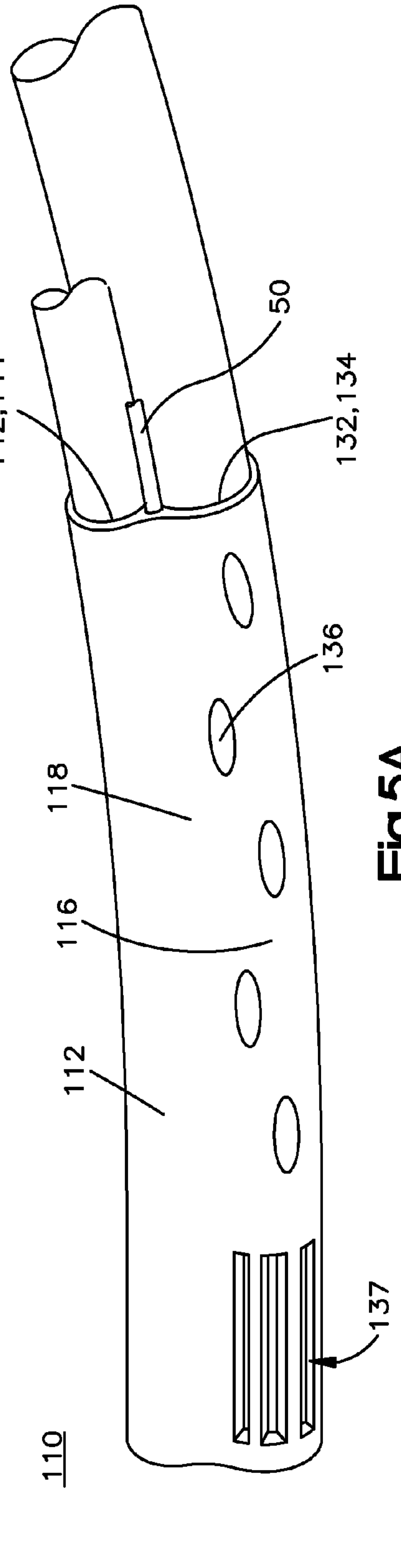
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Fig.5A

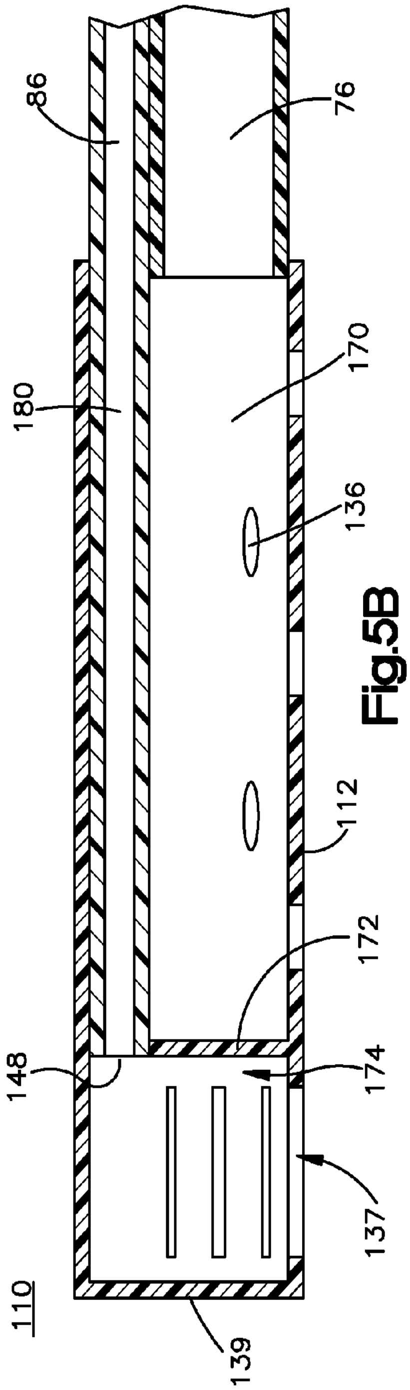
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Fig.5B

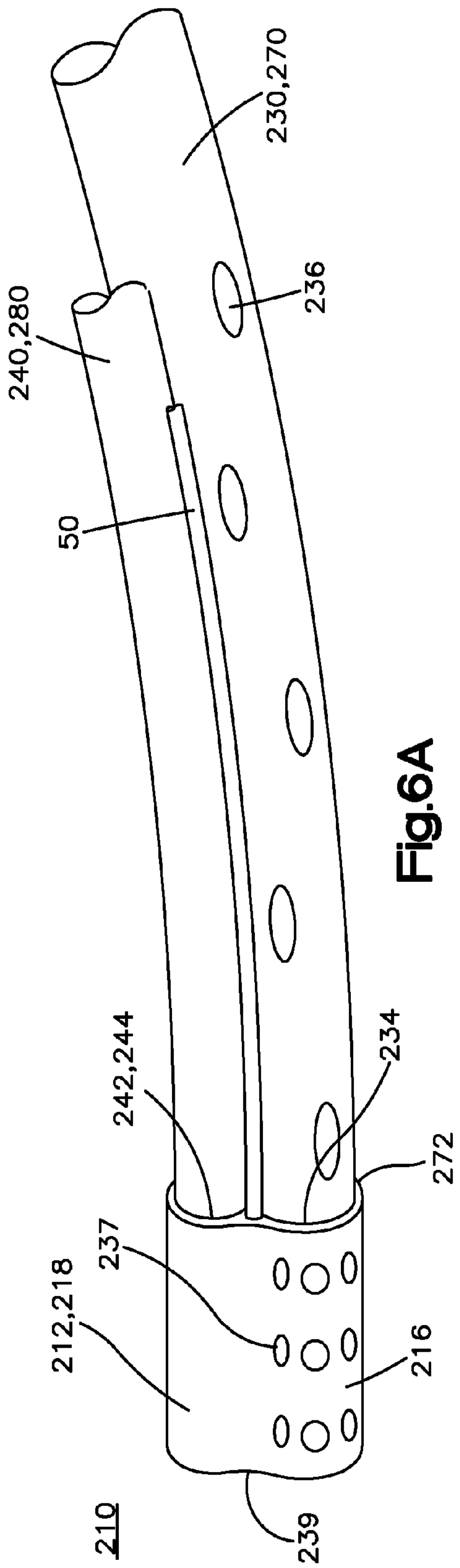
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Fig.6A

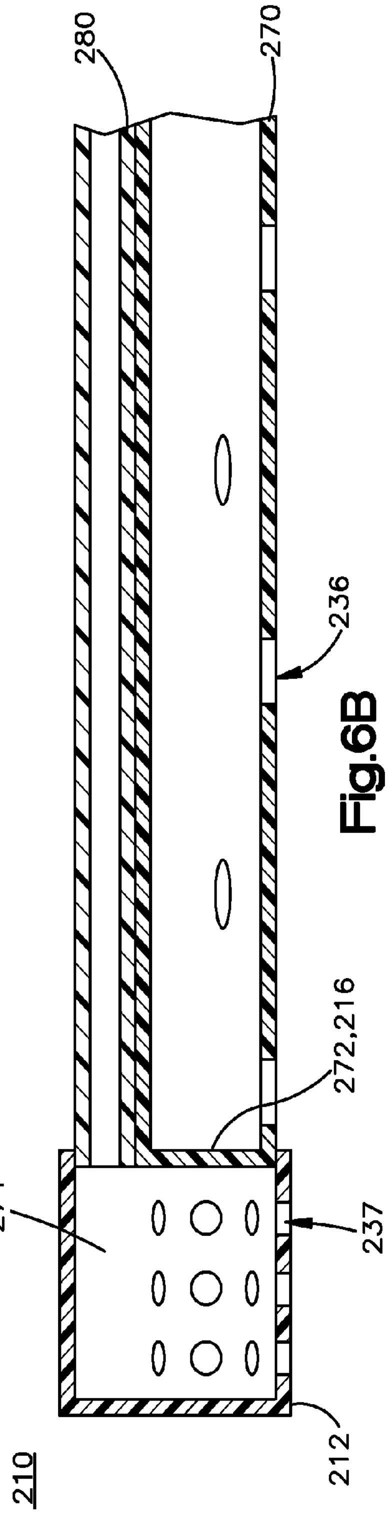
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Fig.6B

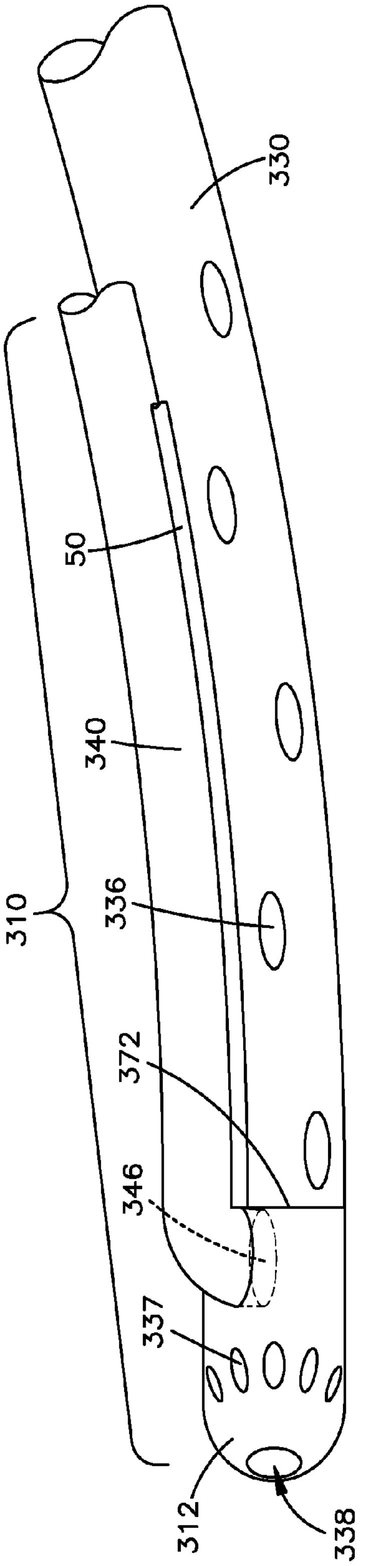

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Fig.7A

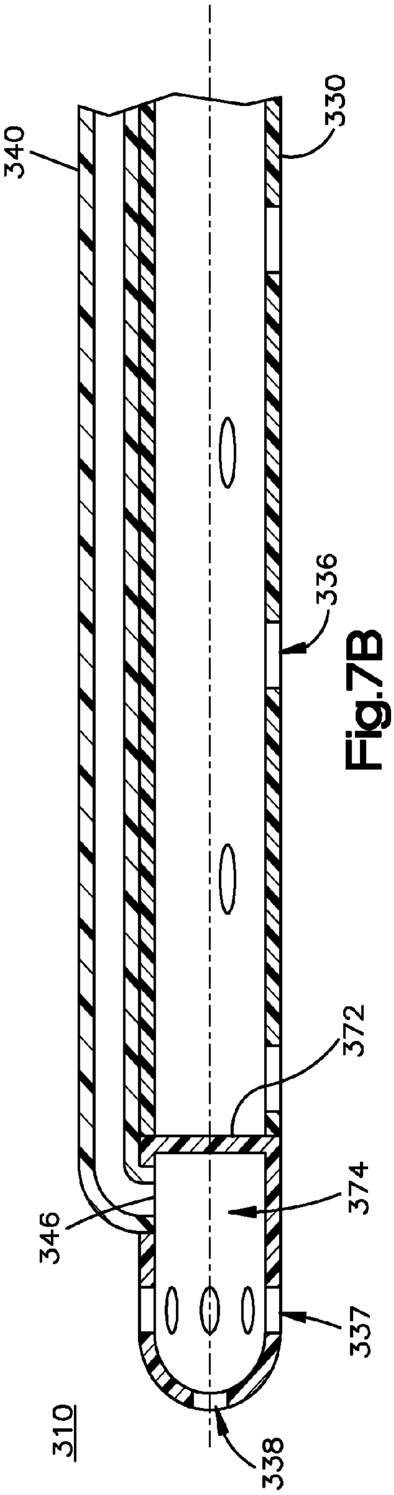

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Fig.7B

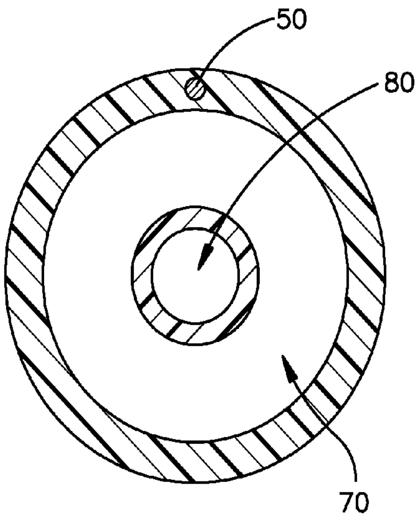

Fig.8A

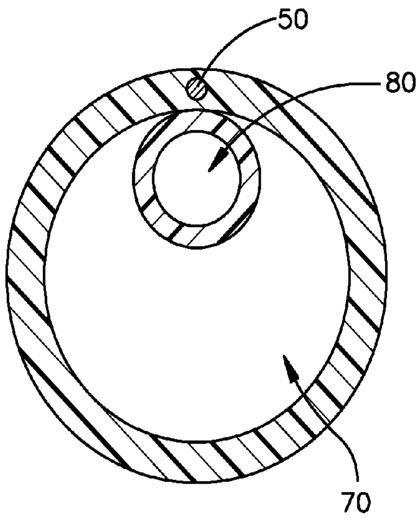

Fig.8B

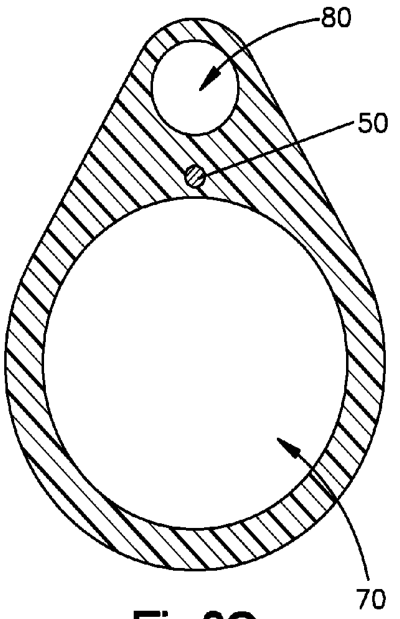

Fig.8C

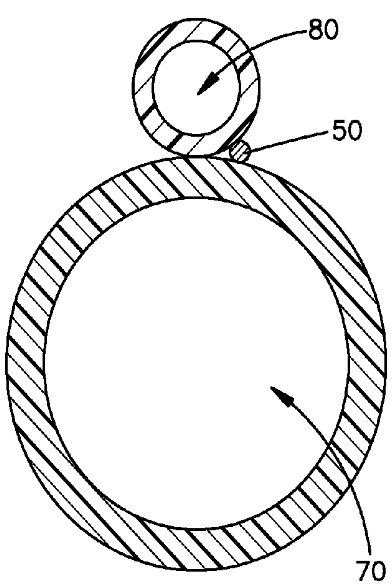

Fig.8D

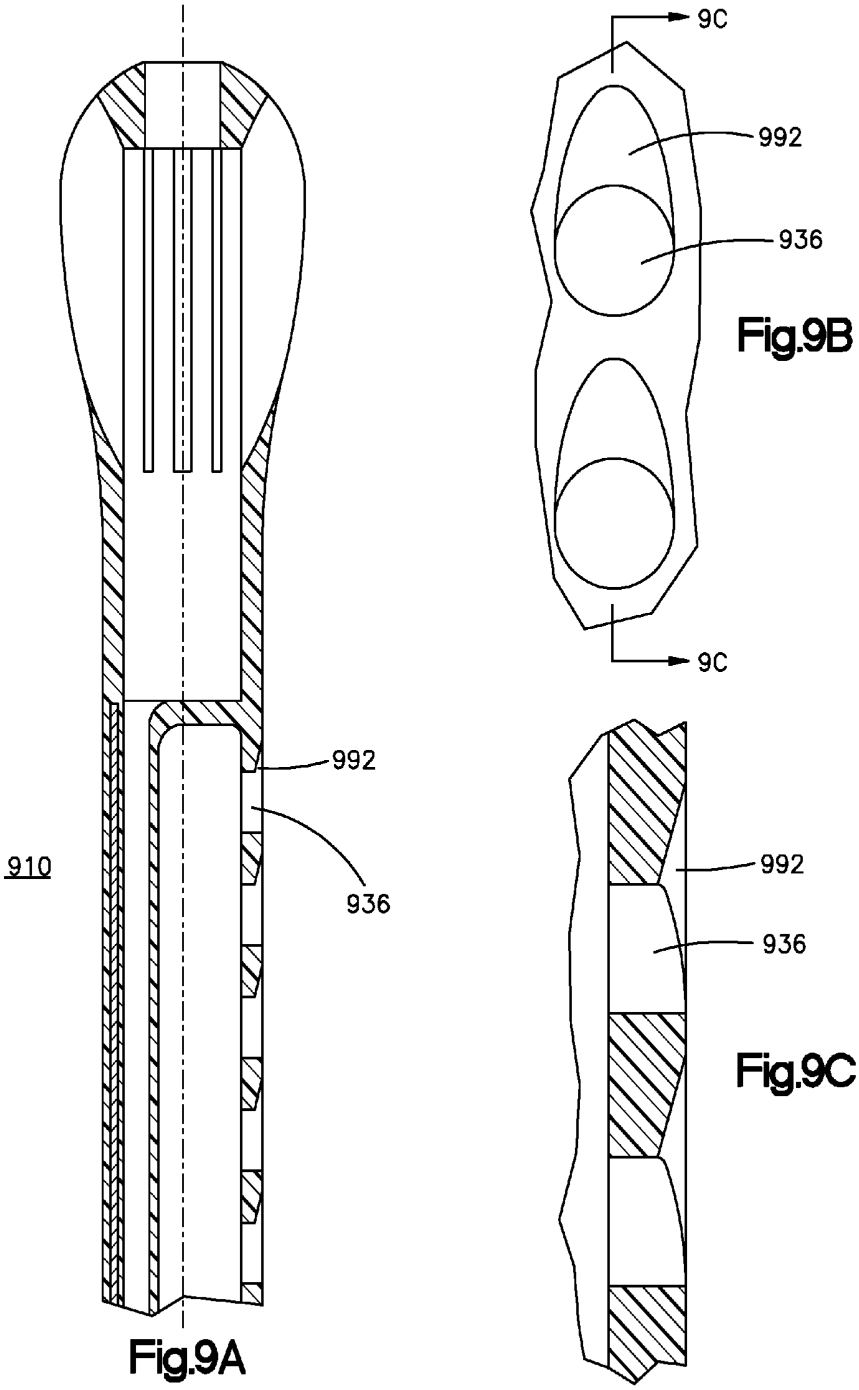

Fig.9A

Fig.9B

Fig.9C

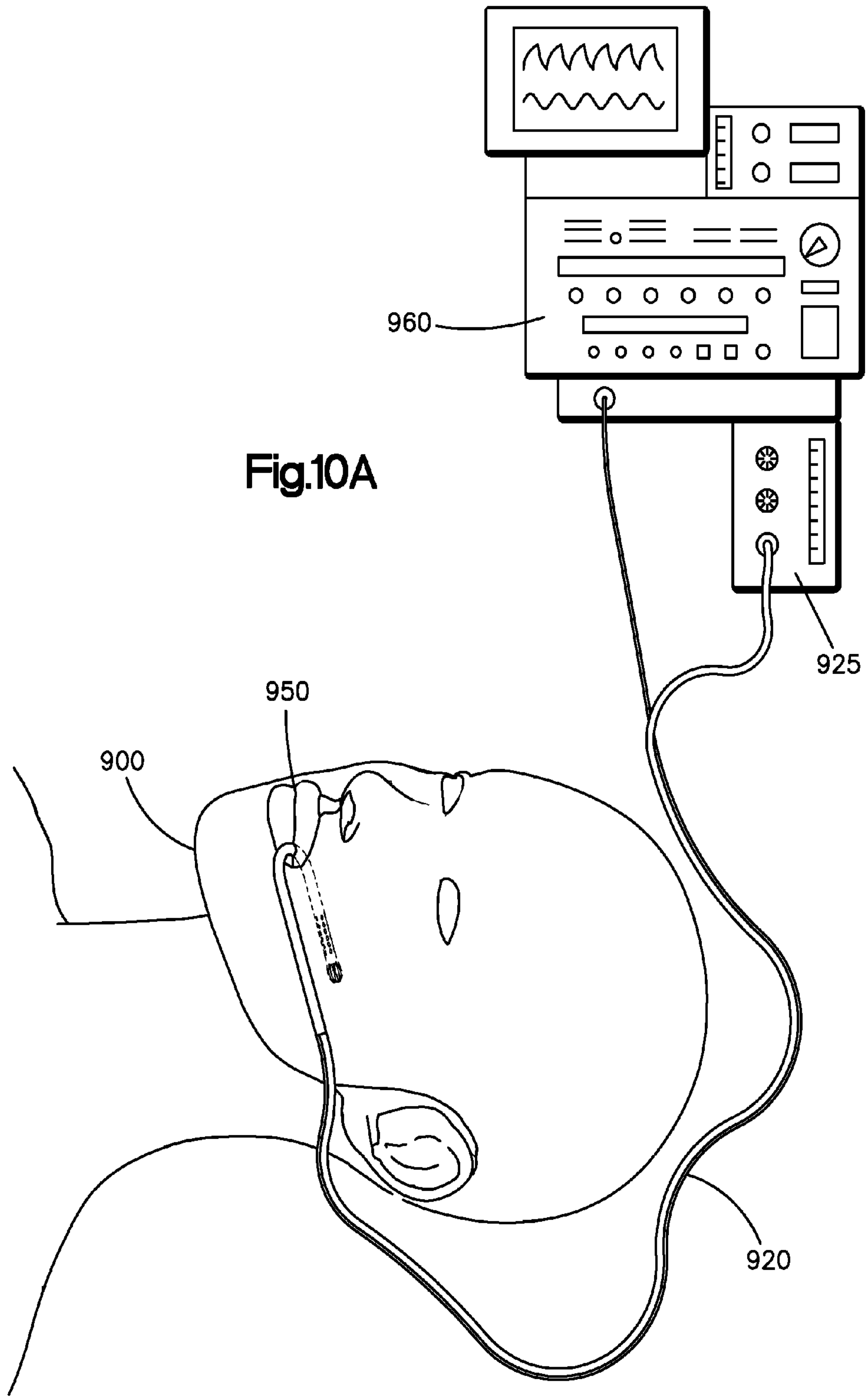

Fig.10A

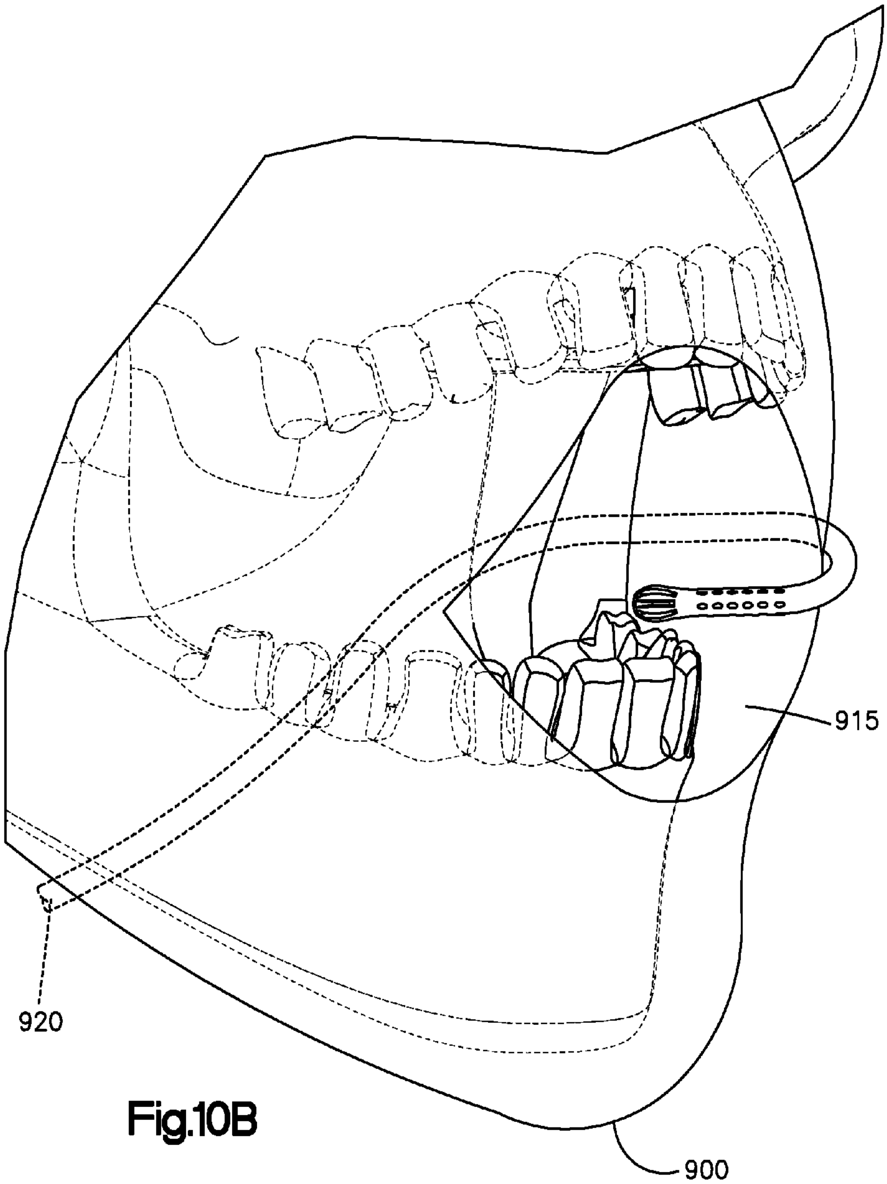

Fig.10B

ORAL CANNULA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application No. 61/886,646, filed Oct. 3, 2013, and U.S. Provisional Application No. 62/009,522, filed Jun. 9, 2014, the disclosures of which are incorporated herein by reference in their entirety.

BACKGROUND

The present invention relates to medical devices and methods, and more particularly to medical devices and methods used while a patient is anesthetized.

Continuous monitoring of exhaled CO2, referred to as capnography, is the conventional standard of care for monitoring a patient's ventilation during operating room procedures. Capnography is also often used during non-intubated procedures that use moderate or deep sedation. A popular means for capnography is the well-known nasal cannula, such as disclosed in U.S. Pat. Nos. 5,335,656 and 6,439,234, which uses one nasal tube to supply oxygen to the sedated patient and another nasal tube to draw end-tidal CO2 for monitoring. A conventional Nasal Cannula (Adult) Salter Style® Ref 4707F from Salter Labs is packaged with several feet of side-by-side oxygen supply tubing and sampling lumen tubing, which terminates at individual, free tubes that are connected to opposing sides of the nasal cannula body.

Typically, the tubes connected to opposing ends of the nasal cannula are looped over the patient's ears, and then the tubes merge into a side-by-side configuration that extends to the oxygen supply and capnography system.

Under certain conditions, the sedated patient may receive insufficient oxygen through the nasal passages, such as when the nasal passages are blocked. An anesthetist might then place the nasal cannula in the patients mouth, such as through a portion of a bite block (if present), and increase the oxygen flow.

SUMMARY

As described herein, an oral cannula for delivering oxygen and sampling end-tidal carbon dioxide includes an oxygen supply lumen having plural outlets near a distal end of the oxygen supply lumen. The oral cannula also includes an end-tidal carbon dioxide (ETCO2) lumen having an inlet near a distal end of the ETCO2 lumen. The ETCO2 lumen and oxygen supply lumen form a unitary oral cannula such that the oxygen supply lumen outlet is spaced apart from the ETCO2 lumen inlet. The oral cannula is adapted for bending or has a bend such that the oral cannula is insertable and retainable in a patient's mouth.

In one embodiment, a method of administering oxygen and sampling end-tidal CO2 (ETCO2) for a patient includes a step of providing oxygen through an oxygen supply tube and through an outlet near a distal end of the oxygen supply tube. The method also includes a step of drawing a gas sample through an ETCO2 tube and through an inlet near a distal end of the ETCO2 tube. The ETCO2 tube is affixed to the oxygen supply tube to form a unitary oral cannula, such that the oxygen tube outlet is spaced apart from the ETCO2 inlet.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1A is an illustration of an oral cannula and oxygen supply tubing and ETCO2 sampling tubing;

FIG. 1B is an enlarged illustration of the oral cannula of FIG. 1A;

FIG. 2A is a perspective view of a an oral cannula according to a first embodiment;

FIG. 2B is an opposite perspective view of the oral cannula of FIG. 2A;

FIG. 3A is a longitudinal cross sectional view of the oral cannula of FIG. 2A;

FIG. 3B is a transverse cross sectional view taken through lines 3B-3B in FIG. 3A;

FIG. 3C is a transverse cross sectional view taken through lines 3C-3C in FIG. 3A;

FIG. 3D is an enlarged view of a portion of the sidewall of the oral cannula of FIG. 2A;

FIG. 3E is cross sectional view taken through lines 3E-3E of FIG. 3D;

FIG. 4A is a perspective view of a co-sheath lumen oral cannula, with hidden structure shown in dotted lines;

FIG. 4B is a perspective view of a coaxial lumen oral cannula, with hidden structure shown in dotted lines;

FIG. 5A is a perspective view of a side-by-side oral cannula;

FIG. 5B is a cross sectional view of the oral cannula of FIG. 5A;

FIG. 6A is a perspective view of another embodiment side-by-side oral cannula;

FIG. 6B is a cross sectional view of the oral cannula of FIG. 6A;

FIG. 7A is a perspective view of another embodiment side-by-side oral cannula;

FIG. 7B is a cross sectional view of the oral cannula of FIG. 7A;

FIG. 8A is an enlarged cross sectional view of coaxial lumens of an oral cannula;

FIG. 8B is an enlarged cross sectional view of co-sheath lumens of an oral cannula;

FIG. 8C is an enlarged cross sectional view of another configuration of co-sheath lumens of an oral cannula;

FIG. 8D is an enlarged cross sectional view of side-by-side lumens of an oral cannula;

FIG. 9A is a cross sectional view of an oral cannula illustrating another embodiment of aperture configuration;

FIG. 9B is an enlarged view of a portion of the sidewall of the oral cannula of FIG. 9A;

FIG. 9C is cross sectional view taken through lines 9C-9C of FIG. 9B;

FIG. 10A is a schematic view of an oxygen supply and capnography system employing the present invention; and

FIG. 10B is an enlarged schematic view of an oral cannula residing in a patient's mouth.

DESCRIPTION OF PREFERRED EMBODIMENTS

The oral cannula embodiments described below have an oxygen supply lumen and an end-tidal carbon dioxide (ETCO2) sampling lumen. Each oral cannula is located or formed at the distal end of oxygen supply tubing and end-tidal carbon dioxide (ETCO2) sampling tubing, which tubing is connected to a conventional capnography and oxygen supply and monitoring system at the end opposite the oral cannula. Conventional luer fittings may be used. Oxygen from the oxygen source (not shown in the figures) and controlled by the anesthetist or control system flows out through the oxygen supply lumen and exits through the oral cannula. Sampling gases are pulled through the oral cannula and the ETCO2 sampling lumen to the capnography system.

FIGS. **1**A and **1**B illustrate an oral cannula that includes a first embodiment oral cannula **10**, oxygen supply tubing **76**, an end-tidal carbon dioxide (ETCO2) sampling tubing **86**, and (preferably) conventional fittings **77** and **87** on respective proximal ends of the tubing. Oral cannula **10** includes an oxygen supply tube lumen **70** and ETCO2 sampling tube lumen **80**. As shown in FIG. **1**A, oxygen supply tube lumen **70** is at a distal portion of oxygen supply tubing **76**; ETCO2 sampling tube lumen **80** is at a distal portion of sampling tubing **86**. In this regard, a portion of the tubing forms the oral cannula, and another portion of the tubing is extraneous to the oral cannula and extends from the oral cannula. A connector **91** is illustrated schematically to encompass any kind of connection or structure for connecting tubing **76**, **86** to lumens **70**, **80**.

The oxygen supply tube **76** and the ETCO2 sampling tube **86** (that is, the portions of the tubing that do not form the oral cannula **10** preferably are several feet long, affixed together in a side-by-side relationship, and terminate at conventional luer fittings **77**, **87** suitable for connection to an oxygen supply and ETCO2 monitoring system. Alternatively, tubing **76** and **86** may be configured in a co-sheath or coaxial configuration.

Tubing **76** and **86** preferably are formed of conventional materials, such as those used for conventional nasal cannula. Among others, suitable plastics are available from Saint-Gobain Performance Plastics Corporation under the TYGON® SE-200 and TYGON name. This tubing has an inert liner and can be used as an O2 delivery line. Tubing **76** and **86** are side-by-side tubes that are affixed together along their entire length, with (preferably) the supply lumen being larger in diameter than the sampling lumen. Other embodiments of the oral cannula described below may have coaxial or other tubing configurations, but the function and materials of the supply and sampling tubing is the same for all embodiments. In this specification, the term "tubing" refers to conventional, flexible tubing (described more fully below); the term "lumen" refers to the structure or the passage formed by the structure of the inventive oral cannula.

As best shown in FIGS. **2**A, **2**B, and **3**A through **3**E, oxygen supply lumen **70** and ETCO2 sampling lumen **80** in the first embodiment are in a co-sheath configuration in which ETCO2 sampling lumen **80** is enclosed within oxygen supply lumen **70** to form a portion of oral cannula body **16**. In this regard, the term "co-sheath" as used in this description refers to a structure in which one tube is contained within another, even if the axes of the tubes do not fall on the same line, including when inner tube is attached to an inner wall of the outer tube. The term "coaxial" as used in this description refers a structure in which tubes are oriented such that the longitudinal axes generally align, including when an inner tube is loose within the outer tube. A coaxial configuration is a subset of a co-sheath configuration.

Body **16** may be integrally formed with the tubing, or body **16** may be a unitary (that is, stand-alone) piece that has openings into which oxygen supply tubing **76** and ETCO2 sampling tubing **86** fit and are attached (including by a separate connector **91** to mate the parts). The sidewall of body **16** includes plural apertures **36** that are in communication with the interior of lumen **70** and tubing **76** such that oxygen supplied by the oxygen source (illustrated in FIG. **10**A) and controlled by the anesthetist or control system flows out of oral cannula **10** through apertures **36**. Body **16** also includes apertures **37**, **38** that are in fluid communication with plenum **74**, sampling lumen **80**, and tubing **86**, such that sampling can be controlled by the ETCO2 monitoring system. In this regard, a distal end of oxygen supply lumen **70** is sealed by a bulkhead **72** such that a distal end of the oral cannula distal to the bulkhead forms a plenum **74**, as best shown in FIG. **3**A. The portion of the oral cannula including the bulkhead and plenum can be referred to as a tip, such as a cap, for example, a bulb. In this regard, the term "tip" in this disclosure is used broadly to refer to any end structure. The tips may be formed of rigid plastic sleeve. Alternatively, the tips may be formed of a soft plastic.

FIG. **3**D is an enlarged view of a portion of the sidewall of the oxygen supply lumen **70** illustrating a configuration of apertures **36**. In this regard, apertures **36** define a centerline that forms an angle A from a longitudinal centerline, which is horizontal as oriented in FIGS. **3**D and **3**E. Preferably, angle A is between 25 and 75 degrees, more preferably between 40 and 60 degrees, and most preferably between 45 and 50 degrees. Further, a distal or upper portion of apertures **36** include a scoop **92** intended to inhibit unintentional blocking of the apertures by contact with a patient's tissues.

FIGS. **9**A, **9**B, and **9**C illustrates an oral cannula **910** having apertures **936** that are oriented perpendicular to the sidewall. Apertures **936** includes a scoop at the distal end, which are intended to inhibit unintentional blocking of the apertures by contact with a patient's tissues. Scoops **92** and **992** are optional, as the present invention encompasses straight holes without scoops.

FIGS. **4**A and **4**B illustrate additional configurations of co-sheathed oral cannula. FIG. **4**A illustrates oral cannula **10'** having a bulkhead **72'** that is a barrier that seals the end of supply lumen **70**. Sampling lumen **80** protrudes through bulkhead **72'** such that plenum **74** is connected to sampling lumen **80** and not in communication with supply lumen **70**. FIG. **4**B illustrates co-axial oral cannula **10"** having a bulkhead **72"**, which functions the same as bulkhead **72'**. Sampling lumen **80** protrudes through bulkhead **72"** at or near the centerline of lumen **70**.

Each bulkhead **72**, **72'**, and **72"** defines the corresponding plenum **74**, **74'**, and **74"**. The text below will employ the reference numerals **72** and **74** to refer to any embodiment of the bulkhead and plenum for ease of description, and reference numeral **10** to refer to any of the embodiment in FIGS. **2**A through **4**B. Apertures **37** are formed in the plenum wall around the body of the plenum **74**. An end aperture **38** may be formed at the distal-most end of oral cannula **10**.

Oxygen from oxygen supply tubing **76** flows within supply lumen **70** on the outside of sampling lumen **80** to exit from apertures **36**. Because bulkhead **72** forms the end of supply lumen **70**, oxygen does not enter plenum **74**. Rather, gas is pulled into plenum **74** through apertures **37** and **38** and through sampling lumen **80** by the action of the suction from the ETCO2 sampling system.

Body **16**, as illustrated in FIG. **1**B, has a bend **13** that may be (optionally) formed by a wire **50** or may be formed upon molding body **16**, as explained more fully below. Body **16** can be formed of a rigid plastic or from a soft plastic, according to the particular design parameters of the oral cannula.

FIG. **8**A illustrates a common coaxial configuration in which the axes are or can lie literally on the same axis. The configuration of FIG. **8**B is, in the nomenclature of this specification, also coaxial if the tube of lumen **80** is not attached to the tube of lumen **70**, as the loose lumens will sometimes be coaxial. If the outside of lumen **70** is adhered to the inside of lumen **80** in FIG. **8**, then the lumens have a co-sheath configuration. FIG. **8**C illustrates another co-sheath configuration in which the outer sheath does not have a circulate cross section. FIG. **8**D illustrates an oral cannula having a side-by-side (that is, not a co-sheath configuration).

FIGS. **5**A and **5**B illustrate an alternative embodiment oral cannula **110** including a tip **112**, such as a cap. Tip **112** is formed by an elongate, supply body **116**, such as a cylindrical or nearly cylindrical supply body, that forms an oxygen supply lumen **170** and a cylindrical, or nearly cylindrical sampling body **118** that forms an ETCO2 sampling lumen **180**. Bodies **116** and **118** preferably are unitary (that is, formed of a single piece of plastic and are not detachable from one another) and side-by-side. Preferably, tip **112** preferably is approximately 1.0 to 3.0 inches long, preferably at least 1.5 inches long, and optionally includes a bend (not shown in FIGS. **5**A and **5**B), to house the entirety of the oxygen supply lumen and ETCO2 sampling lumens of the oral cannula. In this alternative, the tip would be connected to tubing **76** and **86**, and the tip may be formed of a pre-bent rigid plastic, a pre-bent soft plastic, or be supplied with a shaping wire **50**.

Oxygen supply lumen **170** has a proximal end **132** and a distal end **172**. An opening **134** at proximal end **132** is sized to receive oxygen supply tubing **76**. Tubing **76** is inserted into opening **134** and preferably is adhered or welded by conventional means. The sidewall of the body **116** includes plural openings **134** that are in communication with the interior of lumen **170** and tubing **76** such that oxygen supplied by the oxygen source (not shown in Figure) and controlled by the anesthetist or control system flows out of oral cannula **10** through apertures **136**. In this regard, the distal end **172** terminates at a barrier and is sealed such that no oxygen flows out of the distal end of the oral cannula parallel to the longitudinal axis of oral cannula **110** or into plenum **174** (explained below).

ETCO2 lumen **180** has a proximal end **142** and a distal end **148**. An opening **144** at proximal end **142** is sized to receive ETCO2 sampling tube lumen **180**. Lumen **180** is inserted into opening **144** and preferably is adhered or welded together by conventional means. The sidewall of the body **118** preferably has no apertures that open into sampling lumen **180**. Rather, sampling body **118** distally extends past the distal end of the oxygen supply lumen **170** into a plenum **174**. Sampling body **118** at plenum **174** has apertures **137** and (optionally) apertures on the distal end **139** of oral cannula **110** (not shown in FIG. **5**). Apertures **137** preferably are distributed around the circumference or periphery of plenum **174** such that sampling apertures **137** are distal to all of oxygen supply apertures **136**. Apertures **137** enable communication and flow through or near the end of body **118** into the interior of sampling lumen **180** and sampling tubing **86** when pulled by the ETCO2 monitoring system (not shown in the figures). Distal end **139** defines the distal end of oral cannula **110**.

FIGS. **6**A and **6**B illustrate another side-by-side embodiment oral cannula **210** including a tip **212**, an oxygen supply lumen **230**, and an ETCO2 sampling lumen **240**. Tip **212** is formed by a nearly cylindrical supply body **216** that forms a portion of oxygen supply lumen **230** and a cylindrical sampling body **218** that forms a portion of ETCO2 sampling lumen **240**. Bodies **216** and **218** are unitary (that is, formed of a single piece of plastic and are not mutually detachable from one another) and side-by-side. Preferably, tip **212** is between 0.5 inches and 1.5 inches long (measured parallel to the longitudinal axis). In cross section or in an end view, lumens **230** and **240** form a figure eight.

In this regard, oxygen supply lumen **230** of the oral cannula **210** can be formed in part by tip **212** and oxygen supply lumen **270** (that is, a portion of tubing **76**). The ETCO2 sampling lumen **240** of oral cannula **210** can be formed in part by tip **212** and sampling lumen **280** (that is, a portion of tubing **86**). In other words, a portion of tubing **76** and **86** can form a portion of oral cannula **210**. And a portion of tip **212** can form a portion of oral cannula **210**. Alternatively, embodiment oral cannula **210** encompasses an oxygen supply lumen **230** that is short and/or includes only a fitting to close off the end of tubing. In the embodiment shown in FIGS. **6**A and **6**B, body **216** includes an opening recess **234** sized to receive oxygen supply tube lumen **270**, which is inserted into the opening recess **234** and preferably is adhered or welded by conventional means. The sidewall of the tubing that forms supply lumen **270** includes plural apertures **236** that are in communication with the interior of lumen **270** and tubing **76** such that oxygen supplied by the oxygen source and controlled by the anesthetist or control system flows out of oral cannula **210** through apertures **236**. In this regard, the distal end of the supply lumen **270** is sealed by body **216** at a seal **272**.

ETCO2 lumen **240** of tip **212** has an opening **244** at proximal end **242** that is sized to receive ETCO2 sampling tube lumen **280**. Lumen **280** is inserted into opening **244** and preferably is adhered or welded together by conventional means. Sampling body **218** distally extends past the distal end of the oxygen supply lumen **270** to form a plenum **274**. Sampling body **218** has apertures **237** near its distal end **239** and (optionally) apertures on its distal end (not shown in FIG. **6**). Apertures **237** preferably are distributed around the circumference or periphery of plenum **274** and the sampling apertures **237** are distal to all of oxygen supply apertures **236**. Apertures **237** enable communication and flow through or near the end of body **218**, in some circumstances making a right turn, into the interior of sampling lumen **240** and sampling tubing **86** when pulled by the ETCO2 monitoring system. Distal end **239** defines the distal end of oral cannula **210**.

FIGS. **7**A and **7**B illustrate another side-by-side embodiment oral cannula **310** that includes a tip **312**, such as a cap, for example a bulb, that may be formed of a unitary piece having openings into which oxygen supply tubing and ETCO2 sampling tubing fit and are attached or may formed integral with tubing **76** and **86**.

Oral cannula **310** encompasses an oxygen supply lumen **330**, an ETCO2 sampling lumen **340**, a barrier **372**, and a plenum **374**. Tip **312** includes a port **346** that extends through the sidewall of a tip **312** on the distal side barrier **372** to communicate with plenum **374**. Tip **312** forms plenum **374** and includes sampling apertures **337** and end aperture **338**.

The sidewall of the lumen **330** includes plural apertures **336** that are in communication with the interior of supply lumen **330** to enable oxygen to flow out of oral cannula **310**. Oxygen supply lumen **330** terminates at barrier **372**. Sampling lumen **340** extends exterior of the supply lumen **330**, through port **346**. Alternatively (not shown), port **346** can be located on the proximal side of barrier **372** such that port **346** extends through supply lumen **330** to pierce barrier **372** in a configuration like that described for embodiments having a bulkhead. In another alternative (not shown), sampling lumen **340** may extend all the way through supply lumen **330** and terminate only in an aperture at the distal-most end portion of the oral cannula. The latter alternative does not require a bulkhead. Plenum apertures **337** and **338** enable gas to be drawn through apertures **337** and **338**, plenum **374**, port **346**, sampling lumen **340**, and into sampling tubing **86** (not shown in FIGS. **7**A and **7**B).

Oral cannula **310** may be pre-formed with a bend. Tip **312** can be formed of a rigid plastic or from a soft plastic, according to the particular design parameters of the oral cannula and in embodiments in which tip **312** is elongated (not shown), may include a bend, as described elsewhere in this disclosure. Tip **312** can be formed as a separate structure that is fused to lumens **330** and **340**, formed integral with lumen **330** by closing its distal end, or by other means as understood by persons familiar with tubing technology.

For the side-by-side embodiments of FIGS. **5**A through **7**B, the oxygen supply tube **76** and the ETCO2 sampling tube **86** (that is, the portions of the tubing that do not form the oral cannula **110**, **210**, **310**) preferably are several feet long, affixed together in a side-by-side relationship, and terminate at conventional luer fittings **77**, **87** suitable for connection to an oxygen supply and ETCO2 monitoring system. Alternatively, tubing **76** and **86** may be configured in a coaxial configuration.

Tubing **76** and **86** preferably are formed of conventional materials, such as those used for conventional nasal cannula. Among others, suitable plastics are available from Saint-Gobain Performance Plastics Corporation under the TYGON® SE-200 and TYGON name. This tubing has an inert liner and can be used as an O2 delivery line. Tubing **76** and **86** are side-by-side tubes that are affixed together along their entire length, with (preferably) the supply lumen being larger in diameter than the sampling lumen. Other embodiments of the oral cannula described below may have coaxial or other tubing configurations, but the function and materials of the supply and sampling tubing is the same for all embodiments. In this specification, the term "tubing" refers to conventional, flexible tubing (described more fully below); the term "lumen" refers to the structure or the passage formed by the structure of the inventive oral cannula.

The oral cannula described herein can be molded with a bend that resists deformation, may be molded with a bend that is plastically deformable such that the shape of the oral cannula can be adjusted as desired by the anesthetist or other users, may be formed with a shaping wire encapsulated in the plastic, may be formed with a shaping wire exterior to and adhered or mechanically affixed to the body of the cannula, optionally with the wire protected by a protective sheath, or may include other mechanical support (as will be understood by persons familiar with deformable plastic medical devices). In embodiments in which the oral cannula is intended to be deformable, the oral cannula is intended to be deformed by a user's hands. In embodiments in which the oral cannula is intended to be rigid, the oral cannula is stiff enough to resist deformation by the force of a user's hands.

For any of the embodiments in which the oxygen supply lumen and ETCO2 sampling lumen are not fixed in a concentric, coaxial configuration and which have a bend, it is preferred that the sampling lumen be near the inside radius of the bend to enhance the area of the oxygen supply lumen wall that is available for oxygen supply apertures.

As illustrated schematically in FIGS. **10**A and **10**B, a patient **900** can have an oral cannula **10**, which reference numeral is intended to represent any configuration herein, which is shaped and placed in his mouth **915**. For convenience, only first embodiment oral cannula **10** is employed for the description of the overall system. The description of the system applies equally to other embodiments of the oral cannula. Also, while not shown in the figures, an oxygen delivery line **920** from an oxygen source **925** can be split, such as by a Y-splitter or other type of valve, into both an oral cannula line and a nasal cannula line. The nasal cannula line can run to a conventional nasal cannula (not shown), and the oral cannula can simultaneously be used as described above. Such a configuration may be advantageous for situations in which a patient stops breathing through his nose, but is still breathing through his mouth. An ETCO2 sampling line **950** can be connected to a patient monitoring system **960**. The ETCO2 sampling line **950** can also be split.

The structure and function of the oral cannula described in this specification are for illustration purposes and are not intended to be limiting. Rather, it is intended that the claims be limited only to the express structure and function expressly stated in the claims. Further, features of the embodiments described above are not limited to the particular embodiment. Rather, the present invention encompasses any of the features described above in any combination.

What is claimed:

1. An oral cannula for delivering oxygen and sampling end-tidal carbon dioxide, the oral cannula comprising:

an oxygen supply lumen having a proximal end, a distal end and an axial length and plural outlets near the distal end of the oxygen supply lumen, having a continuously non-retrograde oxygen flow path within the cannula for positively-pressurized oxygen-containing gas during operation, and oxygen exits the oral cannula into a patient during use only in a non-retrograde direction; and

an end-tidal carbon dioxide (ETCO2) lumen having a proximal end, a distal end, and an axial length and a plurality of sampling inlets near the distal end of the ETCO2 lumen, the ETCO2 lumen and the oxygen supply lumen form a unitary oral cannula such that the oxygen supply lumen outlet is spaced proximally from the ETCO2 lumen inlet along the axial length of the oxygen supply lumen and the ETCO2 lumen,

wherein the oral cannula is adapted for bending or has a bend such that the oral cannula is insertable and retainable in a patient's mouth.

2. The oral cannula of claim **1** further comprising a cap that forms at least a distal portion of the ETCO2 lumen.

3. The oral cannula of claim **1** wherein the oral cannula includes a cap that forms at least a portion of the oxygen supply lumen.

4. The oral cannula of claim **2** wherein the cap includes at least one sampling aperture near a distal end of the cap that opens into only the ETCO2 lumen, and includes oxygen supply outlets on a sidewall of the cap that open only into the oxygen supply lumen.

5. The oral cannula of claim **1** further comprising a bendable, shape-retaining support wire that is capable of being bent to form the bend.

6. The oral cannula of claim **1** wherein the oxygen supply lumen and ETCO2 lumen are side by side.

7. The oral cannula of claim **2** wherein the cap is a bulb that is coupled to a distal end of the oxygen supply lumen, the cap having at least one aperture that opens only into the ETCO2 lumen.

8. The oral cannula of claim **1** wherein the ETCO2 lumen extends though an outer tube wall of A plenum.

9. The oral cannula of claim **8** further comprising a fitting on the outer tube wall of the plenum such that the ETCO2 lumen extends though the outer tube wall of the plenum and opens into the fitting, the fitting is adapted to receive the ETCO2 sampling tube.

10. The oral cannula of claim **8** wherein the ETCO2 lumen extends through the outer tube throughout the length of the oral cannula and the ETCO2 lumen breaches a bulkhead to open into the plenum.

11. The oral cannula of claim **1** wherein the oxygen supply lumen and ETCO2 lumen are in a co-sheath configuration.

12. The oral cannula of claim **10** wherein a cap forms a least a portion of the ETCO2 lumen and at least a portion of the oxygen supply lumen, the cap having an aperture on a distal end of the cap the opens only into the ETCO2 lumen.

13. The oral cannula of claim **1** wherein a distal end of the oxygen supply lumen is sealed and the oxygen supply lumen includes outlets in a sidewall of the oxygen supply lumen.

14. The oral cannula of claim **1** wherein apertures selected from the group of apertures consisting of the outlets and the inlets include a scoop at a distal surface thereof.

15. The oral cannula of claim **1** wherein at least one of the apertures selected from the group of apertures consisting of the outlets and the inlet is non-orthogonal from the lumen supplying said aperture.

16. A method of administering oxygen and sampling end-tidal CO2 (ETCO2) for a patient, comprising the steps of:

providing oxygen through an oxygen supply tube having a continuously non-retrograde oxygen flow path within the oxygen supply tube for positively pressurized oxygen-containing gas and through an outlet near a distal end of the oxygen supply tube; wherein oxygen exits the oral cannula into a patient during use only in a non-retrograde direction; and

drawing a gas sample through an ETCO2 tube through an inlet located only distally to the distal end of the oxygen supply tube, wherein the ETCO2 tube is affixed to the oxygen supply tube to form a unitary oral cannula, such that the oxygen tube outlet is spaced only proximally from the ETCO2 inlet.

17. The method of claim **16** further comprising a step of bending the oral cannula such that the oral cannula is insertable and retainable in a patient's mouth.

18. The method of claim **17** wherein the step of bending includes bending a support wire.

19. The method of claim **16** wherein the step of providing oxygen includes providing oxygen through a cap that forms at least a portion of an oxygen supply lumen.

20. The method of claim **19** wherein the step of providing oxygen includes providing oxygen through oxygen supply apertures on a sidewall of the cap that open only into the oxygen supply lumen, and the step of drawing the gas sample includes drawing at least one sampling aperture near a distal end of the cap that opens into only the ETCO2 lumen.

21. The method of claim **19** wherein the cap is a bulb that is coupled to a distal end of the oxygen supply lumen, the bulb having at least one aperture that opens only into the ETCO2 lumen, such that the step of providing oxygen includes providing oxygen through the bulb, and the step of drawing the gas sample includes drawing the gas sample through the bulb.

22. The method of claim **16** further comprising a step of inserting and retaining the oxygen supply tube and the ETCO2 tube within a patient's mouth.

23. The cannula according to claim **1**, having a non-co-sheath configuration wherein the oxygen supply lumen is at least partially contained within a separable first wall having an axial length and the ETCO2 lumen is at least partially contained within a separable second wall having an axial length, and the separable first wall and the separable second wall are joined for at least a portion of the axial length of both.

24. The cannula according to claim **23**, wherein the first wall and the second wall and are separable by a user for at least a portion of the axial length of both the first and second wall.

25. An oral cannula for delivering oxygen and sampling end-tidal carbon dioxide, the oral cannula comprising:

an oxygen supply lumen having a proximal end, a distal end and an axial length and plural outlets near the distal end of the oxygen supply lumen, having a continuously non-retrograde oxygen flow path within the cannula for positively-pressurized oxygen-containing gas during operation; and

an end-tidal carbon dioxide (ETCO2) lumen having a proximal end, a distal end, and an axial length and a plurality of sampling inlets near the distal end of the ETCO2 lumen, the ETCO2 lumen and the oxygen supply lumen form a unitary oral cannula such that the oxygen supply lumen outlet is spaced proximally from the ETCO2 lumen inlet along the axial length of the oxygen supply lumen and the ETCO2 lumen, and oxygen exits the oral cannula into a patient during use only in a non-retrograde direction;

wherein the oral cannula is adapted for bending or has a bend such that the oral cannula is insertable and retainable in a patient's mouth.

* * * * *

patsnap

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摘要(译)

用于输送氧气和取样呼气末二氧化碳的口腔套管包括具有多个出口的氧气供应腔和具有入口的呼气末二氧化碳（ETCO2）腔。 ETCO2腔和氧供应腔形成整体口腔插管，使得氧供应腔出口与ETCO2腔入口间隔开。口腔套管适于弯曲或具有弯曲，使得口腔套管可插入并可保持在患者口腔中。