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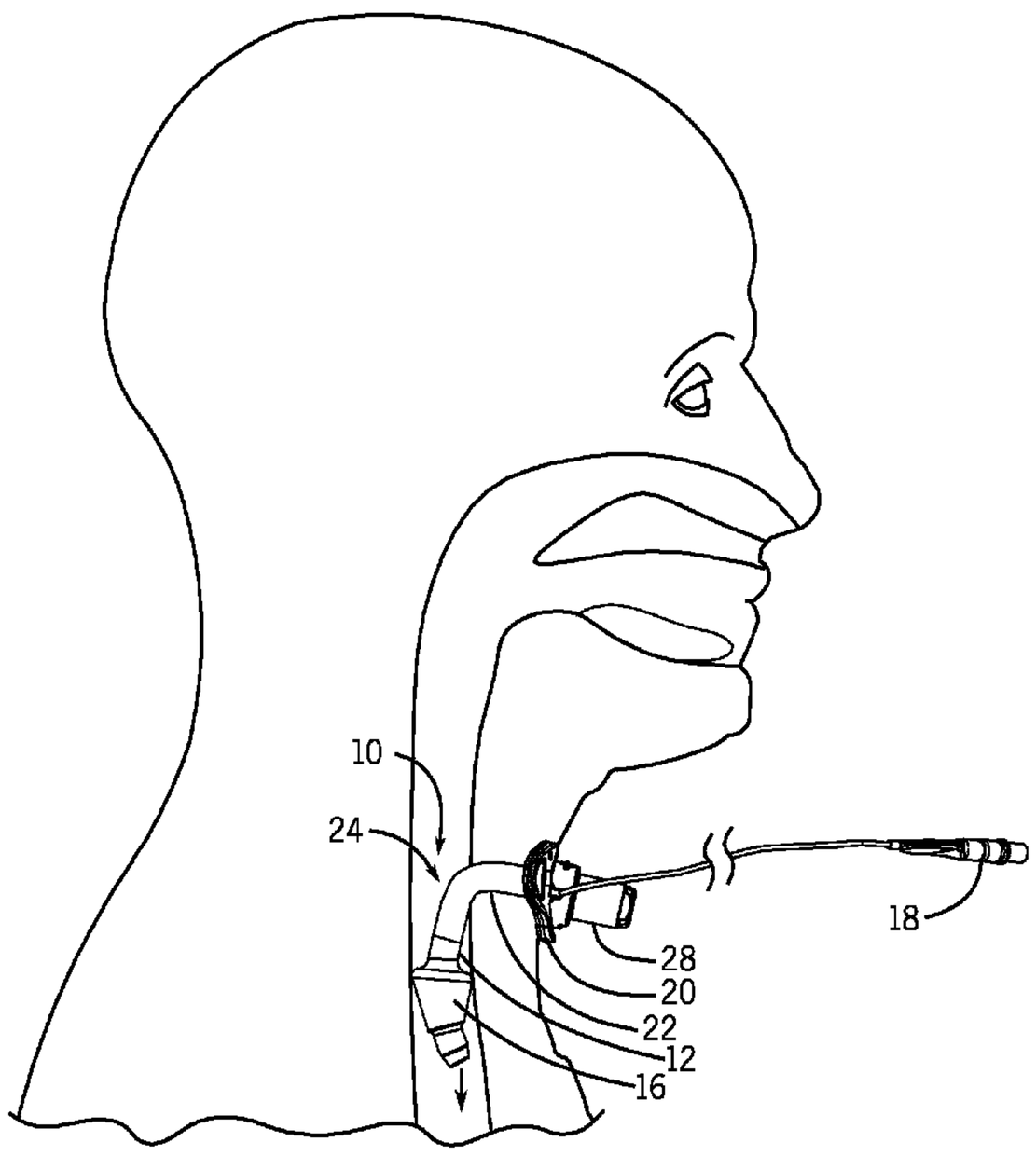

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A tracheal tube assembly includes an outer cannula configured to be positioned in a patient airway and an inner cannula configured to be disposed inside the outer cannula. The tracheal tube assembly further includes a flange member secured about the outer cannula, and an outer cannula connector coupled to a proximal end of the outer cannula. The inner cannula includes a compressible proximal end region that is compressed while secured inside the outer cannula connector.

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(57) Abstract: A tracheal tube assembly includes an outer cannula configured to be positioned in a patient airway and an inner cannula configured to be disposed inside the outer cannula. The tracheal tube assembly further includes a flange member secured about the outer cannula, and an outer cannula connector coupled to a proximal end of the outer cannula. The inner cannula includes a compressible proximal end region that is compressed while secured inside the outer cannula connector.

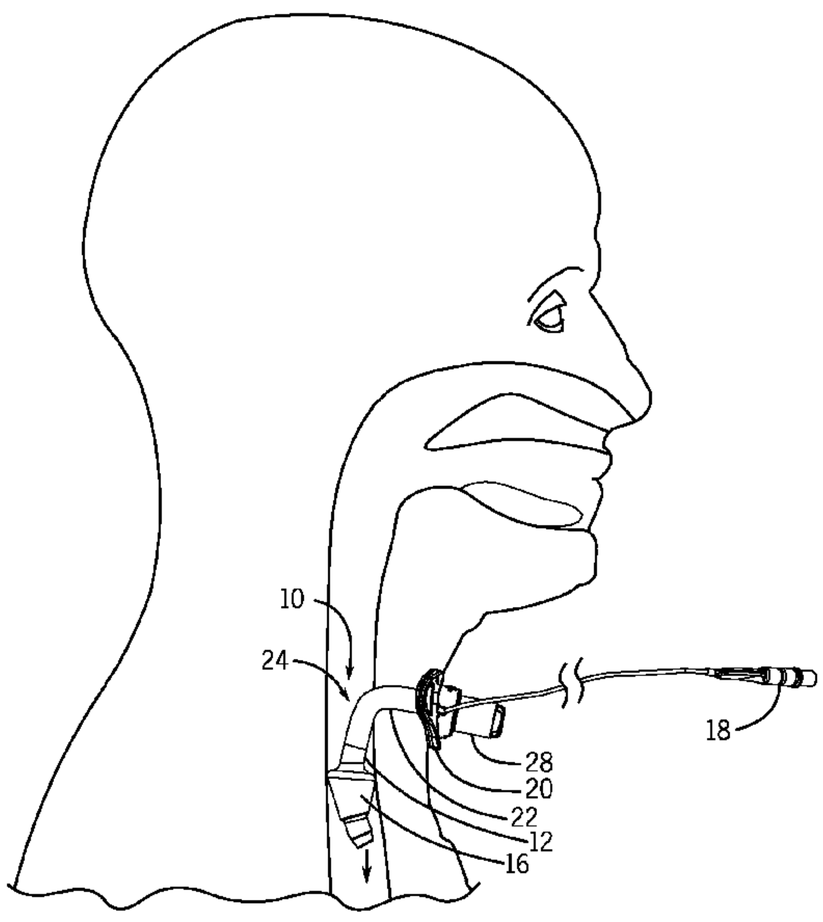

FIG. 1

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COMPRESSIBLE CONNECTOR FOR AN INNER CANNULA

BACKGROUND

The present disclosure relates generally to the field of tracheal tubes and, more particularly, to a tracheal tube including an inner cannula with a compressible end.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

A wide variety of situations exist in which artificial ventilation of a patient may be desired. For short-term ventilation or during certain surgical procedures, endotracheal tubes may be inserted through the mouth to provide oxygen and other gasses to a patient. For other applications, particularly when longer-term intubation is anticipated, tracheostomy tubes may be preferred. Tracheostomy tubes are typically inserted through an incision made in the neck of the patient and through the trachea. A resulting stoma is formed between the tracheal rings below the vocal chords. The tracheostomy tube is then inserted through the opening. In general, two procedures are common for insertion of tracheostomy tubes, including a surgical procedure and a percutaneous technique.

Such tubes may include an inner cannula, such as a reusable inner cannula, or a disposable inner cannula. The inner cannula may be disposed inside the tracheostomy tube and used as a conduit for liquids or gas incoming and outgoing into the patient's lungs. The inner cannula may be removed for cleaning and for disposal of secretions without disturbing the placement of the tracheostomy tube. A connector is typically provided at an upper or proximal end where the tube exits the patient airway, suitable for coupling the ventilator with the inner cannula. In one embodiment, the inner cannula may be removed, cleaned, and reused. In another embodiment, the inner cannula may be

disposable, and a new inner cannula may then be positioned inside of the tracheal tube. By enabling the cleaning and/or replacement of the inner cannula, a ventilation circuit may be kept clean and free of secretions.

Standard connectors have been developed to allow the tracheal tube to then be fluidly coupled to artificial ventilation equipment to supply the desired air or gas mixture to the patient, and to evacuate gases from the lungs. One difficulty that arises in the use of tracheal tubes, and tracheostomy tubes in particular, is in the connection of the tube to the ventilation equipment. For example, an inner cannula may not be installed, or may be installed improperly. This may lead to difficulties with ventilation when a connection is made to ventilation equipment.

There is a need, therefore, for improved tracheal tubes, and particularly for improved tracheostomy tubes. It would be desirable to provide a tube that allows for ease of placement and connection of the inner cannula during ventilation.

BRIEF DESCRIPTION

This disclosure describes a novel tracheal tube designed to respond to such needs with a low insertion force and a high retention force. The tracheal tube may be a tube with a separate inner cannula and outer cannula. The inner cannula includes a compressible end, such as a pinch end, that allows for ease of insertion into the outer cannula. In contrast to other types of inner cannula connectors, such as threaded or snap-on connectors, the disclosed embodiments may provide inner cannulas that may be inserted and connected in a single movement and that also resist axial or rotational displacement relative to the outer cannula. In particular embodiments, the entire proximal end of the inner cannula, including any cap or lip portion, is smaller in diameter than the widest portion outer cannula connector when properly inserted. In this manner, the outer cannula connector forms the connector portion (e.g., a standard 15mm connector) for attachment to upstream medical tubing and/or devices. This is in contrast to disposable inner cannulas that, when inserted into an outer cannula and connector, have integral 15mm connectors. Accordingly, in the disclosed embodiments, the standard connector resides on the outer cannula portion of the tracheal tube, which may allow the outer cannula assembly to be connected to upstream medical tubing with or without an inserted inner cannula.

Further, the compressible end of the inner cannula may be adhered to or otherwise affixed to the inner cannula to form its proximal end region or may be manufactured as a unitary assembly, such as a single molded piece, which may be a cost-effective manufacturing technique. The disclosed tracheal tubes provide improved inner/outer cannula connection while also maintaining standard connections to other medical tubing, such as ventilator tubing.

Thus, in accordance with an aspect, there is described a tracheal tube inner cannula comprising: a conduit configured to be inserted into an outer cannula to transfer gas to a patient, the conduit comprising a flared proximal region, wherein the flared proximal region is configured to be inserted in an outer cannula connector and wherein the flared proximal

region comprises: a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the opposing notches extend from the flared proximal region towards a distal end of the inner cannula such that an outer circumference of a proximal end of the inner cannula is a broken annulus and wherein the first ear and the second ear are configured to be biased towards one another when the flared proximal region is inserted in the outer cannula connector.

Also disclosed herein is a tracheal tube assembly kit that includes an outer cannula configured to be positioned in a patient airway; a flange member secured about the outer cannula; an outer cannula connector coupled to a proximal end of the outer cannula; and an inner cannula configured to be disposed inside the outer cannula comprising: a conduit configured to be inserted into an outer cannula to transfer gas to a patient, the conduit comprising a flared proximal region, wherein the flared proximal region is configured to be inserted in an outer cannula connector and wherein the flared proximal region comprises a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the first ear and the second ear are configured to be biased towards one another when the flared proximal region is inserted in the outer cannula connector.

Also disclosed herein is a tracheal tube inner cannula mold. The mold includes a mold form defining a conduit, wherein the conduit comprises: a distal end; a flared proximal region comprising a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the opposing notches extend from the flared proximal region towards a distal end of the inner cannula such that an outer

circumference of a proximal end of the inner cannula is a broken annulus; a first protrusion formed on an outer surface of the first ear and a second protrusion formed on an outer surface of the second ear, wherein the opposing notches extend distally past the first protrusion and the second protrusion.

BRIEF DESCRIPTION OF THE DRAWINGS

Various aspects of the disclosed techniques may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is a perspective view of a tracheal tube with a compressible inner cannula connector inserted into a patient in accordance with embodiments of the present disclosure;

FIG. 2 is a perspective view of the tracheal tube of FIG. 1;

FIG. 3 is a perspective view of a separate inner cannula and outer cannula assembly of the tracheal tube of FIG. 1;

FIG. 4 is a partial perspective view of a tracheal tube with the inner cannula inserted in the outer cannula connector;

FIG. 5 is perspective view of an inner cannula with a compressible connector in accordance with embodiments of the present disclosure;

FIG. 6 is a partial perspective view of the compressible connector region of the inner cannula of FIG. 5;

FIG. 7 is a top view of the compressible connector region of the inner cannula of FIG. 5

FIG. 8 is a partial perspective view of an inner cannula inserted into the outer cannula connector component;

FIG. 9 is a perspective view of an outer cannula connector component;

FIG. 10 is a cross-sectional view of the outer cannula connector component of FIG. 9; and

FIG. 11 is a perspective view of a tracheal tube assembly including an inner cannula with a compressible connector used in conjunction with an obturator.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present techniques will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

The tracheal tubes as provided herein are disposable rather than reusable, capable of providing differential mechanical ventilation to either or both lungs, and capable of supporting all other functions of standard tracheal tubes (e.g. sealing, positive pressure generation, suctioning, irrigation, drug instillation, etc). The tracheal tubes can be used in conjunction with all acceptable auxiliary airway devices such as (e.g. heat and humidity conservers, mechanical ventilators, humidifiers, closed suction systems, scavengers, capnometers, oxygen analyzers, mass spectrometers, PEEP / CPAP devices, etc). Furthermore, although the embodiments of the present disclosure illustrated and described herein are discussed in the context of tracheal tubes such as tracheostomy tubes, it should be noted that presently contemplated embodiments may include a tracheal tube assembly including an inner cannula with a compressible end used in conjunction with other types of airway devices. For example, the disclosed embodiments may be used in conjunction with a single-lumen tube, an endotracheal tube, a double-

lumen tube (e.g., a Broncho-Cath™ tube), a specialty tube, or any other airway device with a main ventilation lumen. Indeed, any device with a ventilation lumen designed for use in an airway of a patient may include an inner cannula with a compressible end as provided. As used herein, the term "tracheal tube" may include an endotracheal tube, a tracheostomy tube, a double-lumen tube, a bronchoblocking tube, a specialty tube, or any other airway device.

Turning now to the drawings, **FIG. 1** is a perspective view of an exemplary tracheal tube **10** placed in a patient's airway in accordance with aspects of the present disclosure. The tracheal tube assembly **10** represented in the figures is a tracheostomy tube, although aspects of this disclosure could be applied to other tracheal tube structures, such as endotracheal tubes. The application to a tracheostomy tube is apt, however, insomuch as such tubes tend to be worn for longer periods of time and, thus, may include a removable and/or disposable inner cannula disposed inside of an outer cannula **12**, which is useful in maintaining a clean ventilation circuit.

The tracheal tube **10** includes an outer cannula **12** that defines a ventilation lumen and that facilitates the transfer of gases to and from the lungs. The tracheal tube **10** includes an inflatable cuff **16** disposed on the outer cannula **12**. However, certain embodiments of the disclosure may be used in conjunction with cuffless tubes. A proximal end of the tracheal tube **12** may connect to upstream airway devices (e.g., a ventilator) via the appropriate medical tubing and/or connectors. In embodiments that include a cuff **16**, a pilot balloon and inflation line assembly **18** is coupled to the cuff **16**.

The outer cannula **12** is illustrated extending both distally as well as proximally from a flange member **20**. A pair of side wings of the flange **20** extend laterally and serve to allow a strap or retaining member (not shown) to hold the tube assembly **10** in place on the patient. In one embodiment, apertures formed in each side of the flange member **20** allow the passage of such a retaining device. In many applications, the flange member **20** may be taped or sutured in place as well. During intubation, the tracheal tube assembly **10** is placed through an opening formed in the neck and trachea of a patient and extending into the patient airway. In certain embodiments, the tracheal tube assembly **10**

is curved to accommodate the curved tracheal passageway. For example, the outer cannula **12** may be curved in an unbiased state (i.e., outside the patient) such that an inner curve **22** is generally positioned on a ventral side of the patient while the outer curve **24** is positioned on the dorsal side of the patient when the tracheal tube assembly **10** is inserted in the patient. Further, while a distal portion of the outer cannula **12** is inserted within the patient, a proximal portion of the outer cannula **12** forms an outer cannula connector **28, or** As provided herein, the outer cannula connector **28** receives a compressible end region of the inner cannula and forms a secure connection.

FIG. 2 is a perspective view of the tracheal tube assembly **10** showing an inner cannula **30** inserted in the outer cannula **12** and forming a connection with the outer cannula connector **28**. The compressible end region **32** is disposed within the outer cannula connector **28** such that a proximal end **34** is exposed (i.e., is not within the outer cannula connector **28**). The inner cannula **30** is generally coaxial with the outer cannula **12** and is shaped to fit within the outer cannula **12** to form the gas conveying passageway to the patient. In this manner, the inner cannula **30** may be removed and replaced while the outer cannula **12** is retained. This reduces stress on the stoma while permitting cleaning of the passageway.

The inner cannula **30** may be manually inserted into the outer cannula **12.** As shown in **FIG. 3,** the inner cannula **30** may be inserted by pushing the distal end **40** through the proximal end **44** of the outer cannula **12,** e.g., in the direction of arrow **46.** The insertion is complete when the distal end **40** is generally located at or near the distal end **48** of the outer cannula **12.** In certain embodiments, the distal end **40** of the inner cannula **30** terminates short of the distal end **48** of the outer cannula and is disposed entirely within the outer cannula. When the inner cannula **30** is inserted, the compressible end region **32** is disposed at least in part within the outer cannula connector **28.** In embodiments in which the outer cannula forms a curve, such as a Magill curve, the inner cannula **30** may also be curved in a complementary fashion. Accordingly, the insertion may be directional such that proper insertion involves an inner curve **50** of the inner cannula **30** located proximate to or corresponding with the inner curve **22** of the outer cannula **12.** Similarly, the outer curve **52** of the inner cannula **30** will be located

proximate to the outer curve **24** of the outer cannula **12**. The positioning of the inner cannula **30** in the outer cannula **12** may be facilitated by operator technique and, in particular embodiments, with the aid of markings, instructions, or other visual indicators.

The inner cannula **30** forms a conduit from which liquids or gases, including medications, may enter through the proximal end **34**. Both the inner cannula **30** and the outer cannula **12** have dimensions selected to fit easily through the stoma. In practice, a range of such tubes may be provided to accommodate the different contours and sizes of patients and patient airways. Such tube families may include tubes designed for neonatal and pediatric patients as well as for adults. By way of example only, the outer cannula **12** of the tube **10** may range from 4mm to 16mm. The inner cannula **30** may be sized to correspond with an appropriate outer cannula **12**. The outer cannula **12** and the inner cannula **30** may be characterized by their inner diameters (referring to the diameter of the interior of the passageway) or their outer diameters (referring to the diameter as measured from the exterior outside wall to exterior outside wall).

Because the inner cannula **30** fits within the outer cannula **12**, the outer cannula **12** features a larger inner diameter **60** relative to an outer diameter **64** of the inserted portion **54** of the inner cannula **30**. The outer diameter **64** of the inner cannula **30** may be selected to allow sufficient air flow while also fitting comfortably within the outer cannula **12** and allowing for appropriate insertion force. The inner diameter of the outer cannula **30** is less than the outer diameter **64** by the thickness of the walls of the inner cannula **30**. For example, an inner cannula **30** sized to 6.5mm may have an outer diameter **64** of about 6.5mm and an inner diameter of about 5.5mm. In such an embodiment, the inner cannula walls are about 1mm thick in the inserted portion of the inner cannula **30** (e.g., in portions distal of the compressible end region 32). Similarly, a 10mm inner cannula **30** may have an inner diameter of about 9mm. Accordingly, tubes sized to 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0,, or 10mm may feature smaller inner diameters that define the airflow passage.

Further, the inner diameter **62** at the proximal end **44** of the outer cannula **12** is typically larger than the inner diameter **60** and is selected to couple to appropriate tubing.

That is, the outer cannula **12** is narrower in the inserted portion and is wider at the connector. The compressible end region **32** also has a larger outer diameter **70** relative to the inserted portion **54**. In certain embodiments, the compressible end region may flare or taper outwards gradually such that the diameter increases gradually, with the largest diameter **70** at the proximal end **34**. In other embodiment, the compressible end region **32** may include a generally barrel-shaped region with an outer diameter **70**. It should be understood that the compressible end region **32** may change under compression. Accordingly, the outer diameter **70** refers to the uncompressed configuration. Further, in embodiments in which the proximal end **34** forms a broken annulus (i.e., is not a continuous element), the outer diameter **70** refers to a diameter between the solid portions of the proximal end **34**. When the compressible end region **32** is within the outer cannula connector **28**, the outer cannula connector **28** provides a biasing force that compresses the compressible end region **32** into a compressed configuration that is sized to fit within the inner diameter **62** of the outer cannula connector **28**. The outer diameter **70** is larger than a largest outer diameter of the inner cannula **30** in the compressed configuration.

The compressed configuration of the inner cannula **30** is shown in **FIG. 4**, which is a partial perspective view of the proximal region **80** of the tracheal tube assembly **10**. In the compressed configuration, the compressible end region **32** is constrained by the wall **82** of the outer cannula connector **28**. Accordingly, the outer diameter **84** is smaller than the outer diameter **70** (see **FIG. 3**) of the uncompressed configuration. In one embodiment, the outer diameter **84** is about 15mm or slightly smaller. That is, uncompressed outer diameter **70** is about the outer diameter of a 15mm connector. The resulting proximal opening **86** of the inner cannula **30** is also smaller. In a specific embodiment, the material of the compressible end region **32** is selected so that an operator is capable of changing the configuration of the compressible end region **32** through the application of a biasing force. Similarly, the wall **82** of the outer cannula connector **28** is sufficiently strong to maintain the compressible end region **32** in the compressed configuration. In another embodiment, the compressible end region **32** includes one or more notches or openings **90** that facilitate the change from the uncompressed configuration to the compressed configuration. In the compressed

configuration, the gap **92** formed by the opening **90** is smaller than in the uncompressed configuration.

The opening **90** allows the proximal end **34** of the inner cannula **30** to form a smaller compressed diameter **84** under a compression force without wrinkling and while maintaining a generally circular cross-section over the inserted portion of the compressible end region **32** that corresponds with the generally circular cross-section of the outer cannula connector **28.** The size and number of openings **90** may be selected according to the size and manufacturing of the inner cannula **30.** In one embodiment, the compressible end region has two openings **90.** In embodiments with only one opening **90,** the size of the gap **92** in the uncompressed configuration may be relatively larger to facilitate the change from uncompressed to compressed with fewer openings. In another embodiment, if more openings **90** are used, the corresponding gaps **92** may be smaller. That is, in certain embodiments, the total space accounted for in the gaps **92** is about the same regardless of the number of openings. The size of the gaps **92** may be measured in either the compressed or the uncompressed configuration, and may be a largest space between the adjacent portions of the inner cannula wall **94.**

The outer cannula connector **28** may be formed in accordance with industry standards to permit and facilitate connection to ventilating equipment (not shown). By way of example, the outer cannula connector **28** is a 15mm connector, although other sizes and connector styles may be used. Additionally, the tracheal tube assembly **10** may be connected to other medical devices, such as a suction device, a T-junction, a medicine delivery system, and so forth. Indeed, the outer cannula connector **28** may enable the attachment of one or more medical devices to the tracheal tube assembly **10.** To accommodate such a connection, the compressible end region **32** may be formed such that, when inserted, the inner cannula **30** does not interfere with coupling via the outer cannula connector **28.** To that end, in particular embodiments, the widest diameter **84** of the inner cannula **30,** including any protruding portions, is smaller than the widest outer diameter (e.g., 15mm) of the outer cannula connector **28.** It should be understood that, the inserted portions of the compressible end region **32** press against the interior wall **93** of the outer cannula connector **28** and feature an outer diameter that is slightly smaller

(e.g., 12mm or smaller) than the inner diameter of the outer cannula connector **28**. Further, the inner cannula **30** may feature regions with different outer diameters along its length in either configuration.

Because the inner cannula **30** is configured to be inserted and/or removed by an operator, the proximal end **34** may protrude from the outer cannula connector **28** to allow the compressible end region **32** to be manipulated while the inner cannula **30** is in place. For example, the proximal end **34** protrudes proximally or along a rotational axis **95** of the outer cannula connector **28**. The axis **95** is generally orthogonal to the axis **98** along a longest dimension of the flange member **20**. When inserted in the patient, the inner cannula **30** may be positioned so that the operator grips the proximal end and pushes laterally (e.g., along the axis **98**). Accordingly, the openings **90** may be positioned to correspond with a dorsal and ventral side of the tube **10** (e.g. to correspond with the inner curve **50** and the outer curve **52** of the inner cannula, see **FIG. 3**) when inserted to encourage lateral compression. In other embodiment, the openings **90** may be positioned to encourage dorsal-ventral compression.

FIG. 5 is a perspective view of an inner cannula **30** in the uncompressed configuration. In the depicted configuration, the proximal end **34** assumes its largest unbiased outer diameter **70**. When force is applied along arrows **110**, the first ear **112** and the second ear **114** move towards one another (e.g., along axis **98**, see FIG. **4**) and the gaps **92** formed by the openings **90** decrease as the compressible end region **32** assumes the smaller, compressed outer diameter **84** (see FIG. **4**). For example, an application of 5N of force or less may be applied to achieve sufficient compression to insert the inner cannula **30**. In other embodiments, the compressible end region **32** may form a single gripping structure or more than two ears.

FIG. 6 is a detail view of the compressible end region **32**. In particular embodiments, the compressible end region **32** may include mating features that couple to complementary features on the interior wall **93** of the outer cannula connector **28** (see **FIG. 4**). Such mating features may prevent rotational movement of the inner cannula **30** relative to the outer cannula connector **28**. In addition, the mating features may provide

additional alignment to facilitate correct alignment of the curve of the inner cannula **30** with the curve of the outer cannula **12** (see **FIG. 3**). As depicted, the mating features may be protrusions, such as protrusion **122** formed on an exterior surface **120** of the inner cannula **30**. The protrusion **122** may be formed in any suitable shape or combination of shapes, such a rounded bump, a ramp shape, a pyramid structure, etc. Further, the compressible end region **32** may include any number of protrusions **122** positioned about a circumference. For example, the compressible end region **32** may include two protrusions **122** that oppose one another. In specific embodiments, opposing protrusions **122** may be circumferentially centered on the ears **112** and **114**. In such embodiments, the protrusions **122** may serve as guides for an operator to press against to bias the ears **112** and **114** towards one another. In another embodiment, the protrusions **122** may be about 90 degrees from opposing notches **90**. In another embodiment, respective protrusions **122** may be provided as a partial ring with an arc having less than **45°** of circumference of the compressible end region **32**. In another embodiment, the protrusion **122** may form a ring about the circumference of the compressible end region **32**.

It should be understood that the mating features may also be implemented as recesses or a combination of protrusions and recesses. The size of the protrusion **122** may be selected to fit into a corresponding recess in the outer cannula connector **28** and may be less than a thickness of the wall of the outer cannula connector **28**. In one embodiment, the protrusion **122** may protrude less than about 1mm, less than about 1.5mm or less than about 2mm from the exterior surface **120**. In particular embodiments, the protrusions **122** protrude less than a widest diameter **70** in an uncompressed configuration. Alternatively, the protrusion **122** may fit into complementary windows formed in the outer cannula connector. In such embodiments, the protrusion **122** may be larger. The inner cannula **30** may also include additional support structures, such as one or more ribs **124**. In the depicted embodiment, the rib **124** may provide structural support to the protrusion **122**. In addition, the compressible end region **32** may feature regions of varying outer diameters that form a slope **126**. The slope **126** may be formed proximate to the protrusion **122** to facilitate insertion of the relatively larger protrusion **122** into the inner cannula connector **28**.

FIG. 7 is a top view of the inner cannula **30** showing the position of two opposing protrusions **122** relative to the proximal end **34**. The position of the protrusions **122** may be measured from the midpoint **130** or the distal-most point **132**. In one embodiment, the distance **140** from the proximal end **34** of the inner cannula **30** to the distal-most point **132** of the protrusion **122** may be selected to place the protrusion **122** within the interior of the inner cannula connector **28** (see **FIG. 4**). In another embodiment, the protrusion **122** may be positioned relative to a distal terminus **142** of opposing openings **90**. As depicted, the openings **90** are generally oriented along the rotational axis **95**. However, it should be understood that the openings **90** may be irregularly shaped. Accordingly, the distal terminus may be the distal-moist point of the opening **90** from the proximal end **34**.

In one embodiment, the protrusion **122** is located proximally relative to the distal terminus **142**. In other words, the distance **140** is less than a distance **144** (the distance from the proximal end **34** to the distal terminus **142**). Further, the ratio of the distance **140** to the distance **144** may be selected such that the protrusions **122** are generally closer to the distal terminus **142** than the proximal end **34**. For example, the ratio may be greater than 0.5 or greater than 0.75. Such an implementation may allow the protrusions **122** to be biased sufficiently toward one another to ease insertion in the inner cannula connector **28**. That is, if the proximal end region **32** is flared, positions closer to the distal terminus **142** may be within smaller diameter regions. In certain embodiments, the distal terminus **142** is also positioned within the inner cannula **28**. Depending on the size and length of the inner cannula connector **28**, in particular embodiments, the distance **144** may be less than about 15mm, less than about 12mm, less than about 10mm, less than about 9mm, less than about 8mm, less than about 7mm, less than about 6mm, or less than about 5mm.

The proximal end **34** may also terminate in a lip **150** that is formed in the wall **94**. The relatively thicker lip **150** may also extend at least partially towards the distal terminus **142** and terminate in an abutment surface **152**. The abutment surface **152** is configured to abut the proximal end **44** of the inner cannula connector and prevent further movement of the inner cannula **30** distally, which may assist in aligning the inner

cannula **30** within the outer cannula **12**. In certain embodiments, a distance **160** from the abutment surface **152** to the proximal end **34** is less than the distance **140** and the distance **144**. In particular embodiments, the distance **160** is less than 50% of the distance **144** or is less than 50% of the distance **140**. In a particular embodiment, the distance **160** is about 4mm. Further, in another embodiment, the distance between a midpoint **130** and the abutment surface **152** may be less than the distance **160**, e.g., may be about 3mm.

As noted, the proximal end **34** of the inner cannula **30** is positioned outside of the outer cannula connector **28**, which facilitates operator manipulation of the inner cannula **30**. **FIG. 8** is a partial perspective component view of the interaction between the inner cannula connector **28** and the proximal end **34**. The position of the abutment surface **152** determines how much the proximal end **34** protrudes from the proximal end **44** of the inner cannula connector **28**. A more distal abutment surface **152** results in greater protrusion. The length **170** of the protrusion may be about 4mm or less. In other embodiments, the length **170** of the protrusion is selected to avoid interference with couplings formed by the outer cannula connector **28**. In addition, the inner cannula **30** may include features that facilitate gripping by an operator. The thickness **172** of the lip **150** may be selected to maintain the desired outer diameter **84** and also form a gripping end. The lip **150** may be slightly thicker than the inserted portion of the compressible end region **32**.

In certain embodiments of the present techniques, the inner cannula **30** is retained in place by the compression force of the compressible proximal end **32** against the interior surface **93** of the inner cannula connector **28**. That is, the force against the inner cannula connector **28** reflects the material and geometric properties of the compressible end region **32** and a tendency of the compressible end region **32** to return to a default uncompressed configuration. In one embodiment, the compression force is sufficient to form a seal between the compressible end region **32** and the inner cannula connector **28**. In one embodiment, the compressible end region **32** has one or more mating features that may align the inner cannula **30** within the outer cannula **12** and/or may prevent rotational dislodgment.

FIG. 9 is a perspective view of an inner cannula connector **28** that includes complementary features to such mating features. The inner cannula connector **28** is typically coupled to the outer cannula **12** (see **FIG. 1**) at its distal end **180**. The inner cannula connector **28** may also include distal features **182** for coupling to the flange member **20** (see **FIG. 1**), such as threading connectors, snap-in features, and/or one or more windows or recesses to facilitate heat bonding. In certain embodiments, the inner cannula connector **28** may include one or more recesses (e.g., recesses **184** and **186**) that are sized and shape to accommodate complementary protrusions on a compressible end region **32** of an inner cannula **30**. It should be understood that the complementary features may be selected based on the characteristics of the mating features. Accordingly, if the mating features are protrusions, the complementary features are recess or windows and vice versa. Similarly, the position of the complementary features may be selected to facilitate proper alignment and insertion of the inner cannula **30**. **FIG. 10** is a cross-section of the inner cannula connector **28** of **FIG. 9**, showing the position of the recess **184**.

It is envisioned that the tracheal tube assembly **10** as provided herein may be provided as an assembly and/or as a kit. A kit may include a packaging that encloses an inner cannula **30** sized for an outer cannula **12**, which may include an affixed outer cannula connector **28** and flange member **20**. The kit may also include a neck strap for retaining the tracheal tube **10** in place. The kit may also include an obturator **190**, shown in **FIG. 11**. Other components of the kit may include a cap configured to be placed on a proximal end **34** while the obturator **190** is in use and that may be part of the obturator **190**. The tube assembly **10** components (e.g., outer cannula **12**, flange member **20**, outer cannula connector **28**, cuff **16**, and pilot balloon assembly **18**) may be assembled prior to *in situ* assembly of the inner cannula **12** into the outer cannula **14**. Indeed, the user or clinician may perform final assembly of the tracheal tube **10** by selecting a desired inner cannula **30** from a selection of inner cannulas and then inserting the inner cannula **30** into the outer cannula **12** prior to intubation. Thus assembled, the tracheal tube **10** may then be inserted into the patient's trachea.

Components of the tube assembly **10** may be manufactured according to suitable techniques. For example, the inner cannula and/or outer cannula **12**, including the outer cannula connector **28**, may be molded, overmolded, two shot molded, computer numerical control (CNC) machined, milled, or otherwise formed into the desired shape. In one embodiment, a mold or mold form may be used to manufacture the inner cannula **30**. The tracheal tube inner cannula mold comprises a mold form defining a conduit, wherein the conduit comprises: a distal end and a flared proximal region. The mold form also defines a flared proximal region includes a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region. The opposing notches extend from the flared proximal region towards a distal end of the inner cannula such that an outer circumference of a proximal end of the inner cannula is a broken annulus. The mold form also defines a first protrusion formed on an outer surface of the first ear and a second protrusion formed on an outer surface of the second ear such that the opposing notches extend distally past the first protrusion and the second protrusion in a conduit formed using the mold form.

In one embodiment, the mold or other manufacturing technique may facilitate a speckled outer surface of the inner cannula **30**, which may facilitate insertion. One or more components may be manufactured of materials such as a polyethylene (e.g., low density polyethylene), polypropylene, PTFE, expandable PTFE, polyvinyl chloride (PVC), a PEBAX silicone, a polyurethane, thermoplastic elastomers, a polycarbonate plastic, a silicon, or an acrylonitrile butadiene styrene (ABS). In particular embodiments, the material of the inner cannula **30** may be selected to be 60 Shore D.

While the disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the embodiments provided herein are not intended to be limited to the particular forms disclosed. Indeed, the disclosed embodiments may not only be applied to airway devices, but these techniques may also be utilized for connections between inner and outer conduits for other types of medical devices and medical connective tubing. Rather, the various embodiments may cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims.

EMBODIMENTS IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A tracheal tube inner cannula comprising:

a conduit configured to be inserted into an outer cannula to transfer gas to a patient, the conduit comprising a flared proximal region, wherein the flared proximal region is configured to be inserted in an outer cannula connector and wherein the flared proximal region comprises:

a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the opposing notches extend from the flared proximal region towards a distal end of the inner cannula such that an outer circumference of a proximal end of the inner cannula is a broken annulus and wherein the first ear and the second ear are configured to be biased towards one another when the flared proximal region is inserted in the outer cannula connector.

2. The tracheal tube inner cannula of claim 1, comprising:

a first protrusion formed on an outer surface of the first ear and a second protrusion formed on an outer surface of the second ear, wherein the opposing notches extend distally past the first protrusion and the second protrusion.

3. The tracheal tube inner cannula of claim 2, wherein the first protrusion and the second protrusion correspond with lateral sides of the inner cannula when the inner cannula is positioned in the patient.

4. The tracheal tube inner cannula of claim 2, wherein the first protrusion and the second protrusion protrude at least 1mm from an outer surface of the inner cannula.

5. The tracheal tube inner cannula of any one of claims 1 to 4, wherein the opposing notches correspond with a ventral side and a dorsal side of the inner cannula when the inner cannula is positioned in the patient.

6. The tracheal tube inner cannula of any one of claims 1 to 5, wherein the proximal end of the inner cannula comprises a lip having a greater wall thickness than an adjacent portion of the flared proximal region.

7. The tracheal tube inner cannula of claim 6, wherein the lip extends at least partially down a U-shape formed by the opposing notches.

8. A tracheal tube assembly kit comprising:

an outer cannula configured to be positioned in a patient airway;

a flange member secured about the outer cannula;

an outer cannula connector coupled to a proximal end of the outer cannula; and

an inner cannula configured to be disposed inside the outer cannula comprising:

a conduit configured to be inserted into an outer cannula to transfer gas to the patient, the conduit comprising a flared proximal region, wherein the flared proximal region is configured to be inserted in an outer cannula connector and wherein the flared proximal region comprises a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the first ear and the second ear are configured to be biased towards one another when the flared proximal region is inserted in the outer cannula connector.

9. The assembly kit of claim 8, comprising a first mating feature formed on an outer surface of the first ear and a second mating feature formed on an outer surface of the second ear, wherein the opposing notches extend distally past the first mating feature and the second mating feature.

10. The assembly kit of claim 9, wherein the outer cannula connector comprises corresponding features formed on an inner surface of the outer cannula connector and configured to mate with the first mating feature and the second mating feature.

11. The assembly kit of claim 10, wherein the first mating feature and the second mating feature are protrusions and wherein the corresponding features on the outer cannula connector comprise windows that extend through a wall of the outer cannula connector.

12. The assembly kit of claim 10 or 11, comprising an obturator.

13. The assembly kit of any one of claims 8 to 12, wherein the first ear and the second ear are biased when inserted in the outer cannula connector with a biasing force that is directed along an axis defined by a longest dimension of the flange.

14. The assembly kit of any one of claims 8 to 13, wherein the opposing notches terminate within the interior of the outer cannula connector when the inner cannula is inserted in the outer cannula connector.

15. A tracheal tube inner cannula mold comprising:

a mold form defining a conduit, wherein the conduit comprises:

a distal end;

a flared proximal region comprising a first ear and a second ear separated by opposing notches formed in a wall of the flared proximal region, wherein the opposing notches extend from the flared proximal region towards a distal end of the inner cannula such that an outer circumference of a proximal end of the inner cannula is a broken annulus;

a first protrusion formed on an outer surface of the first ear and a second protrusion formed on an outer surface of the second ear, wherein the opposing notches extend distally past the first protrusion and the second protrusion.

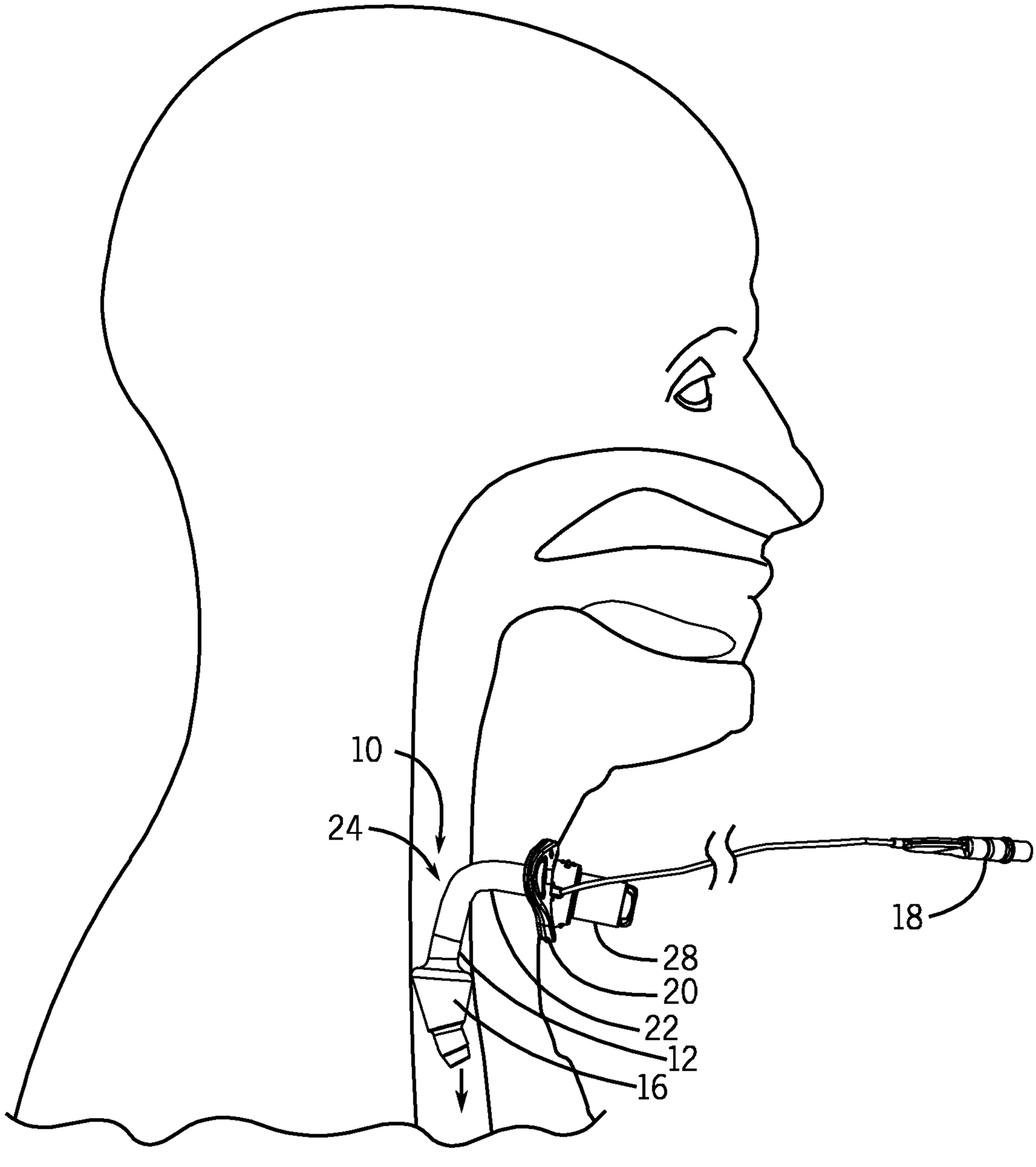
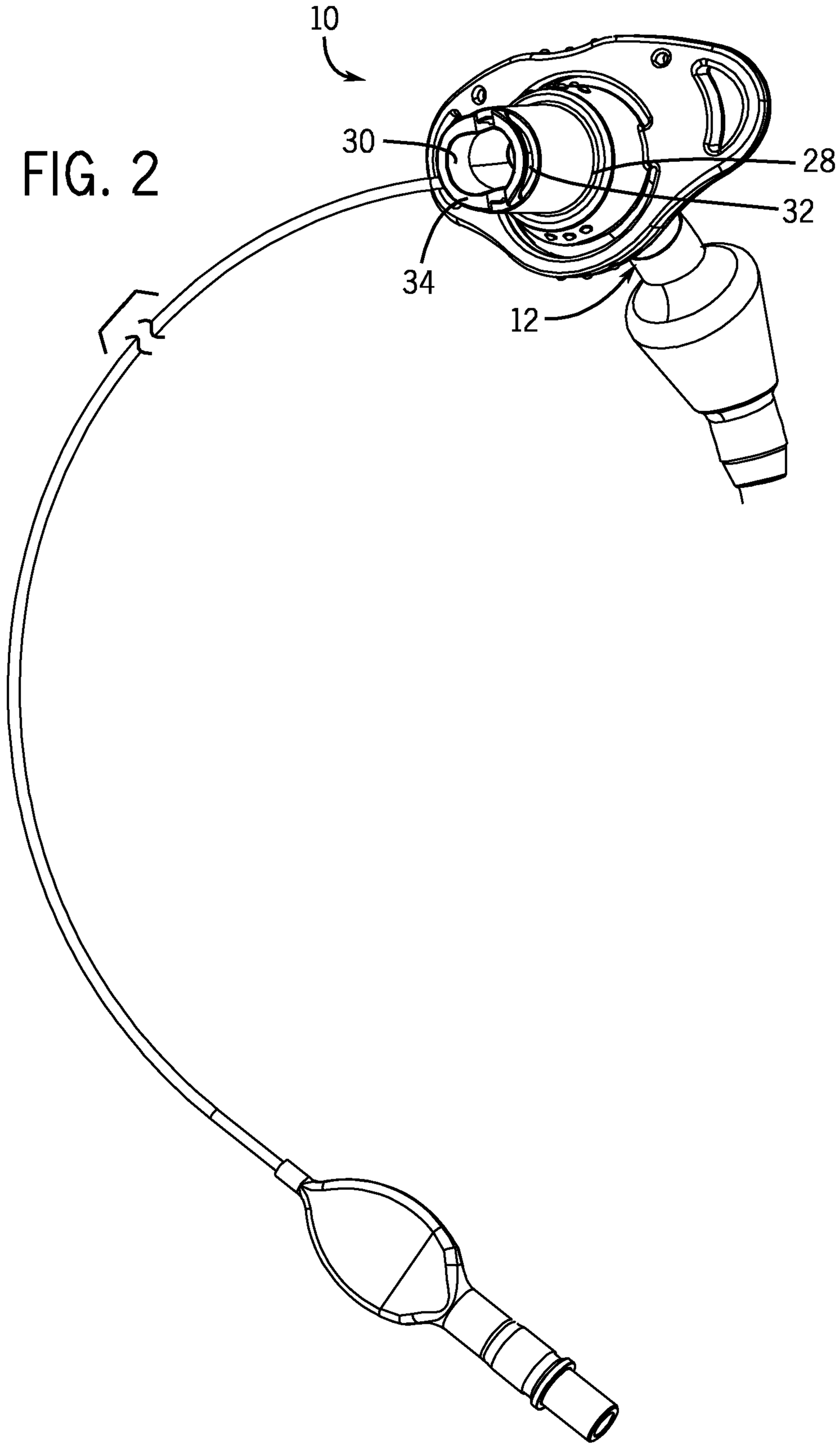


FIG. 1

FIG. 2



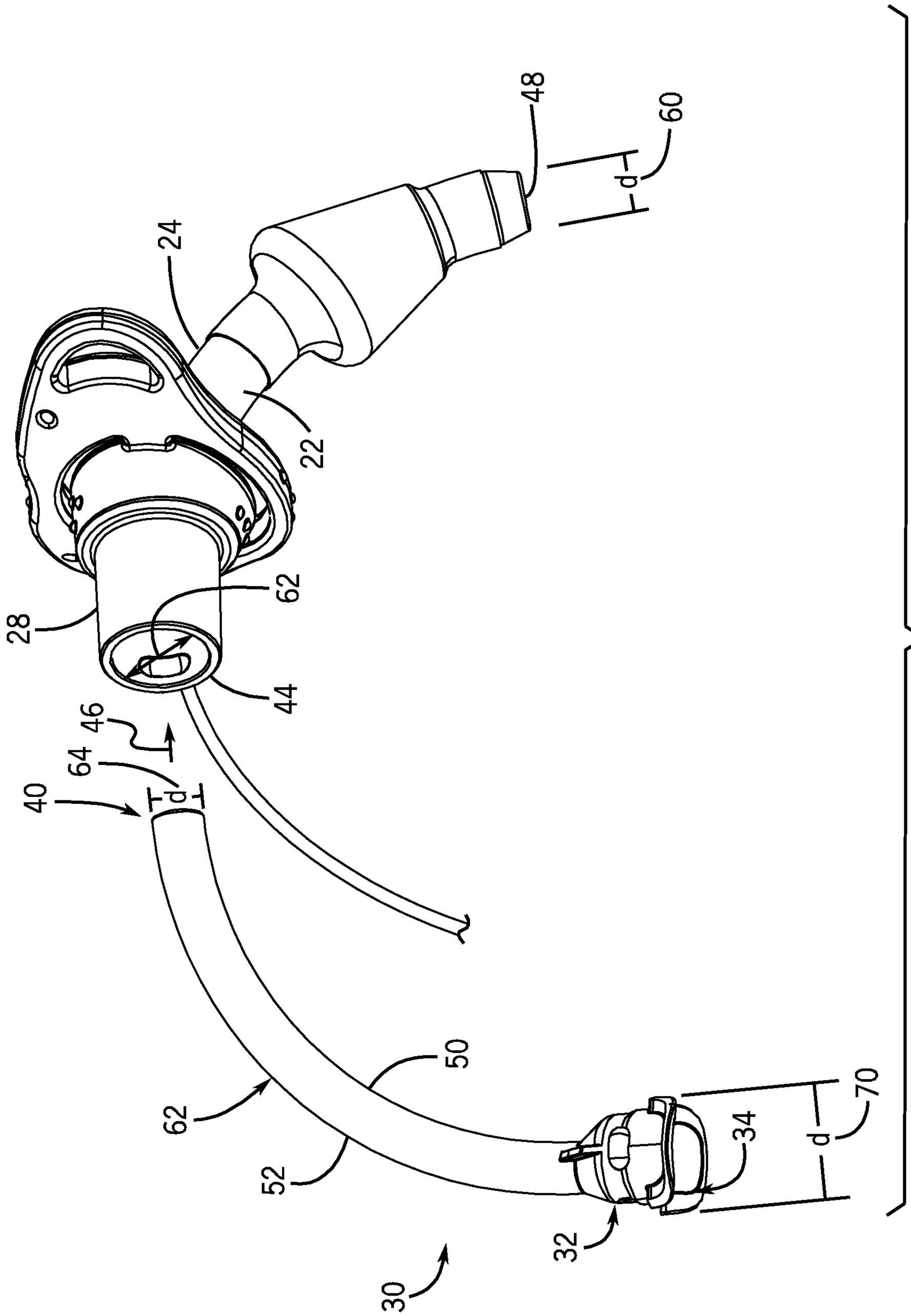


FIG. 3

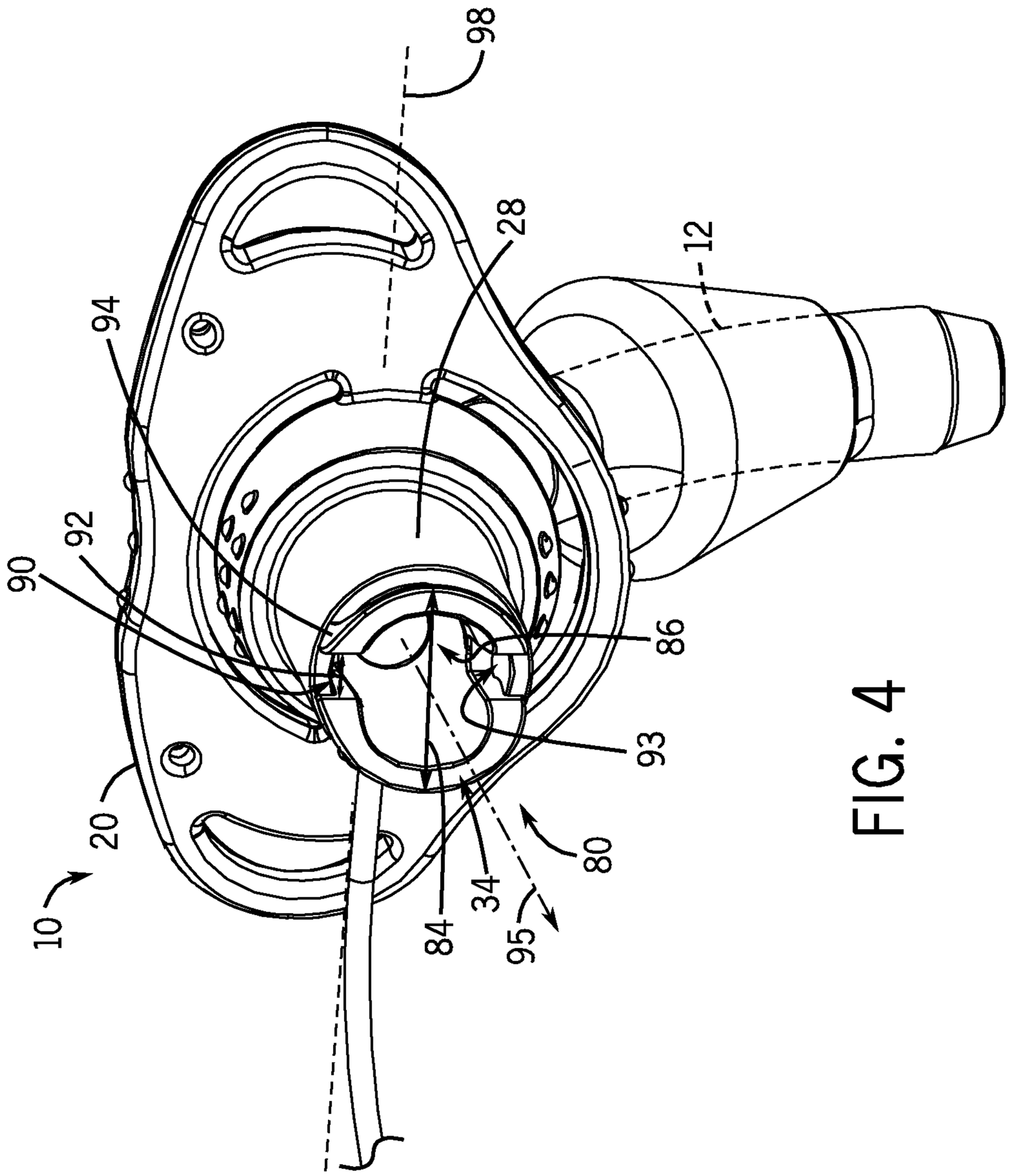


FIG. 4

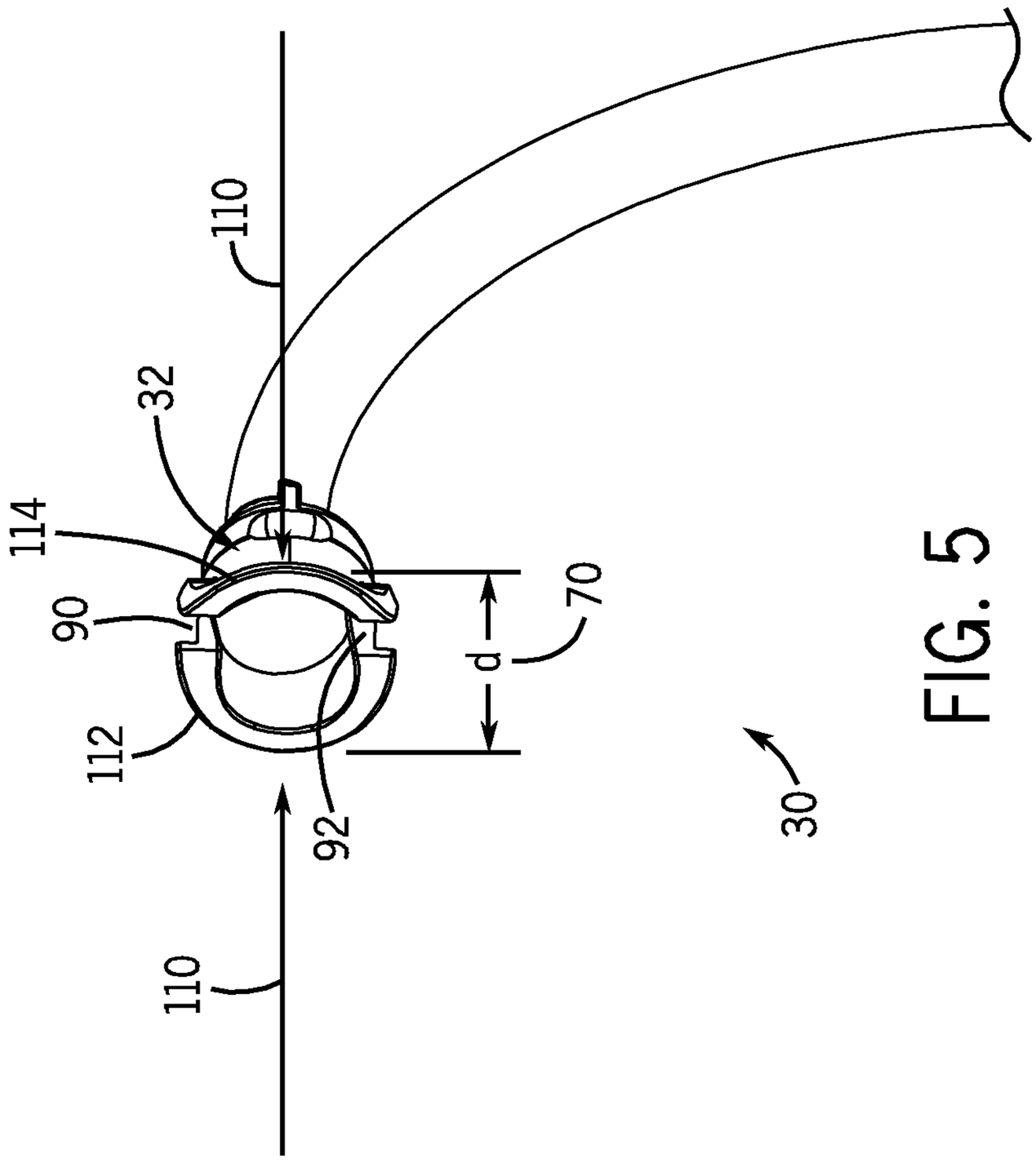


FIG. 5

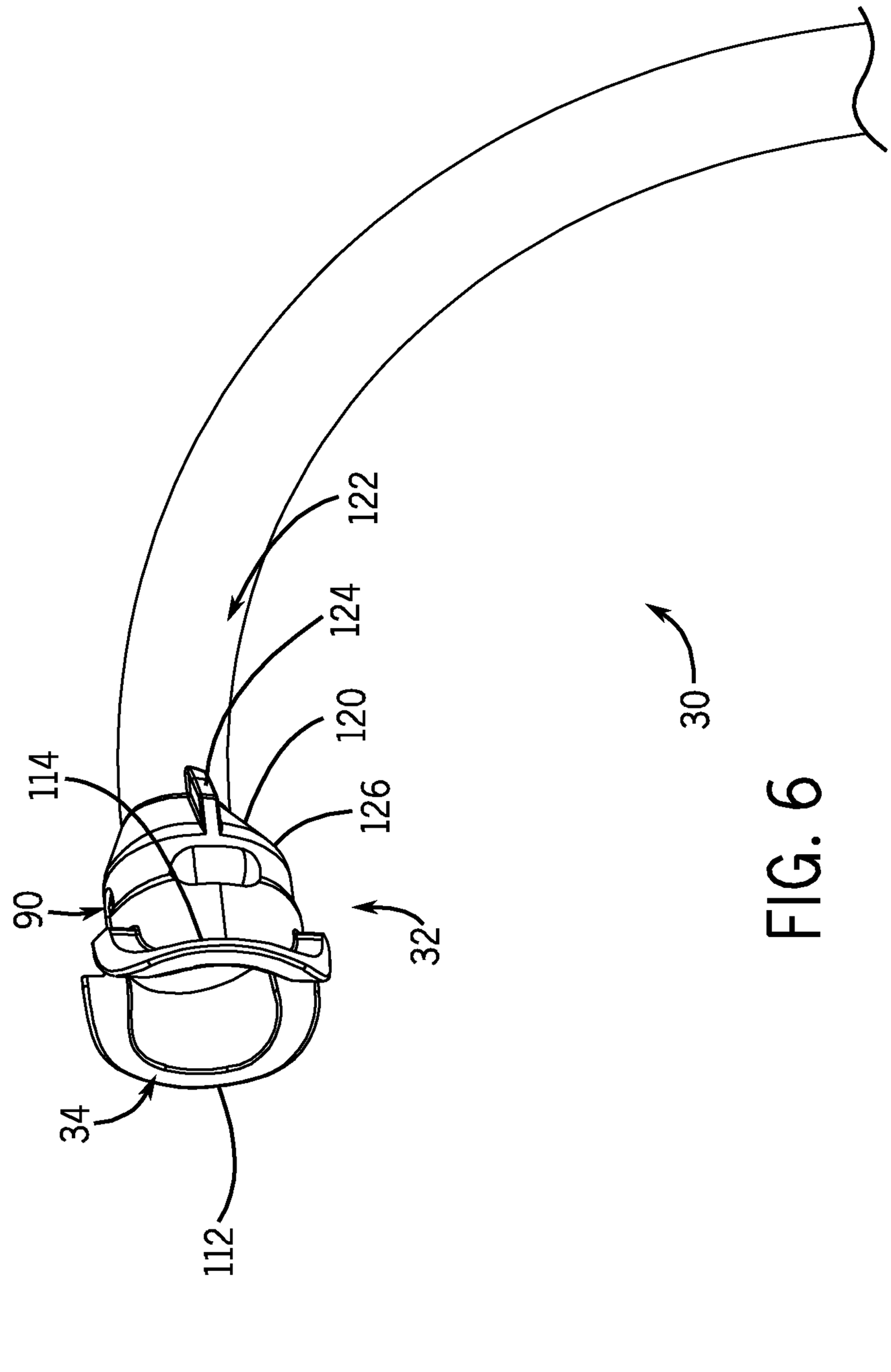


FIG. 6

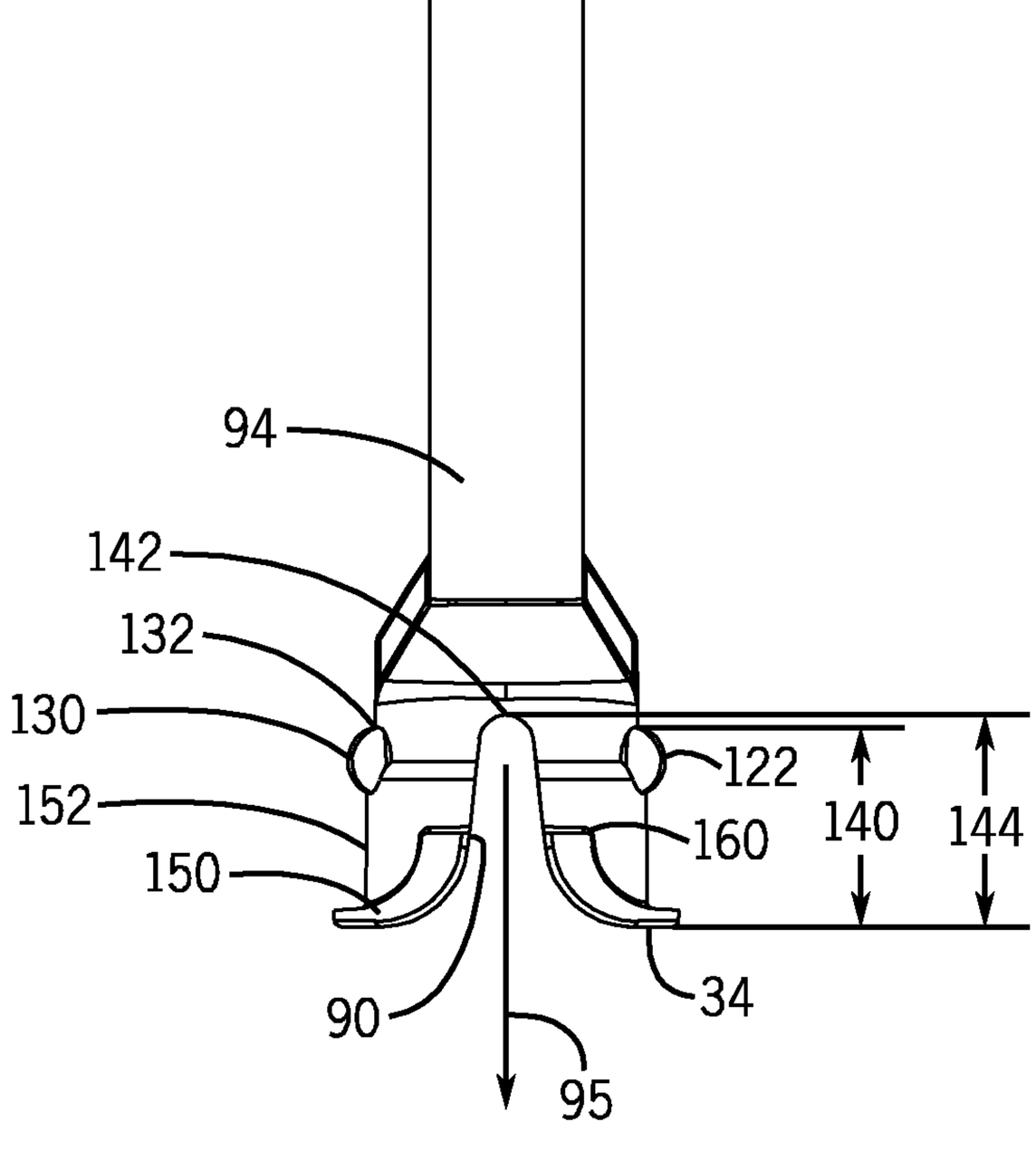


FIG. 7

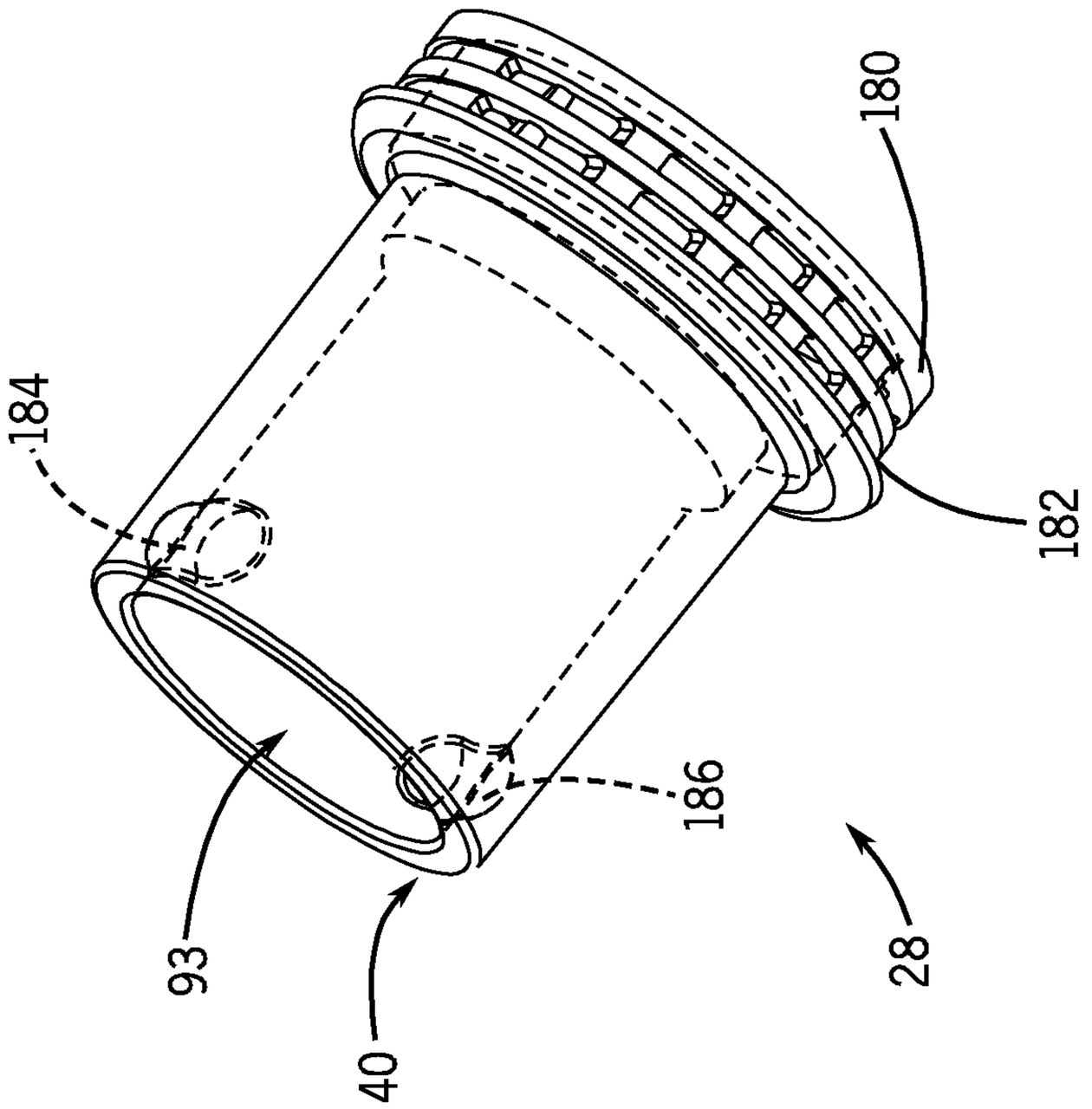


FIG. 9

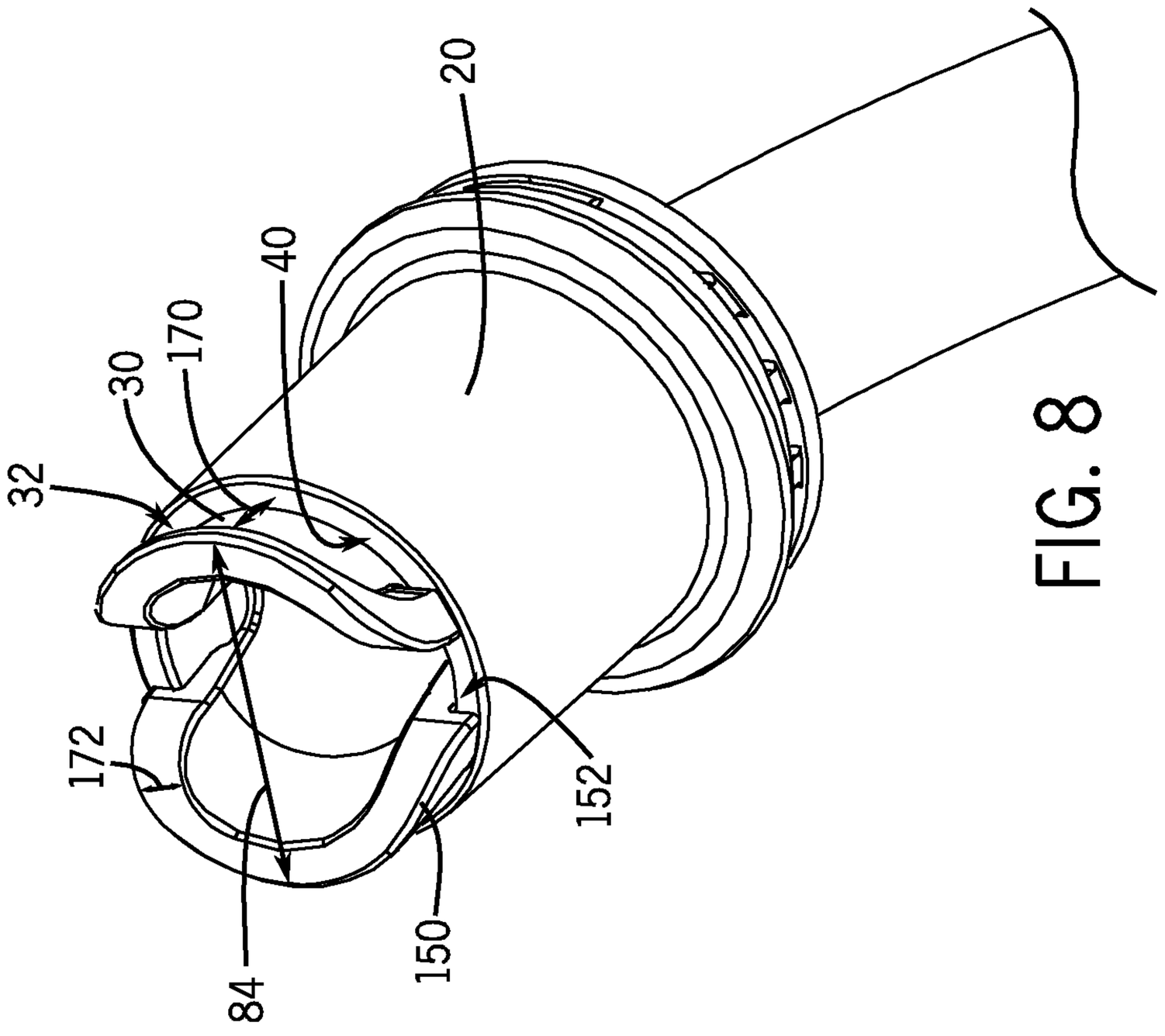


FIG. 8

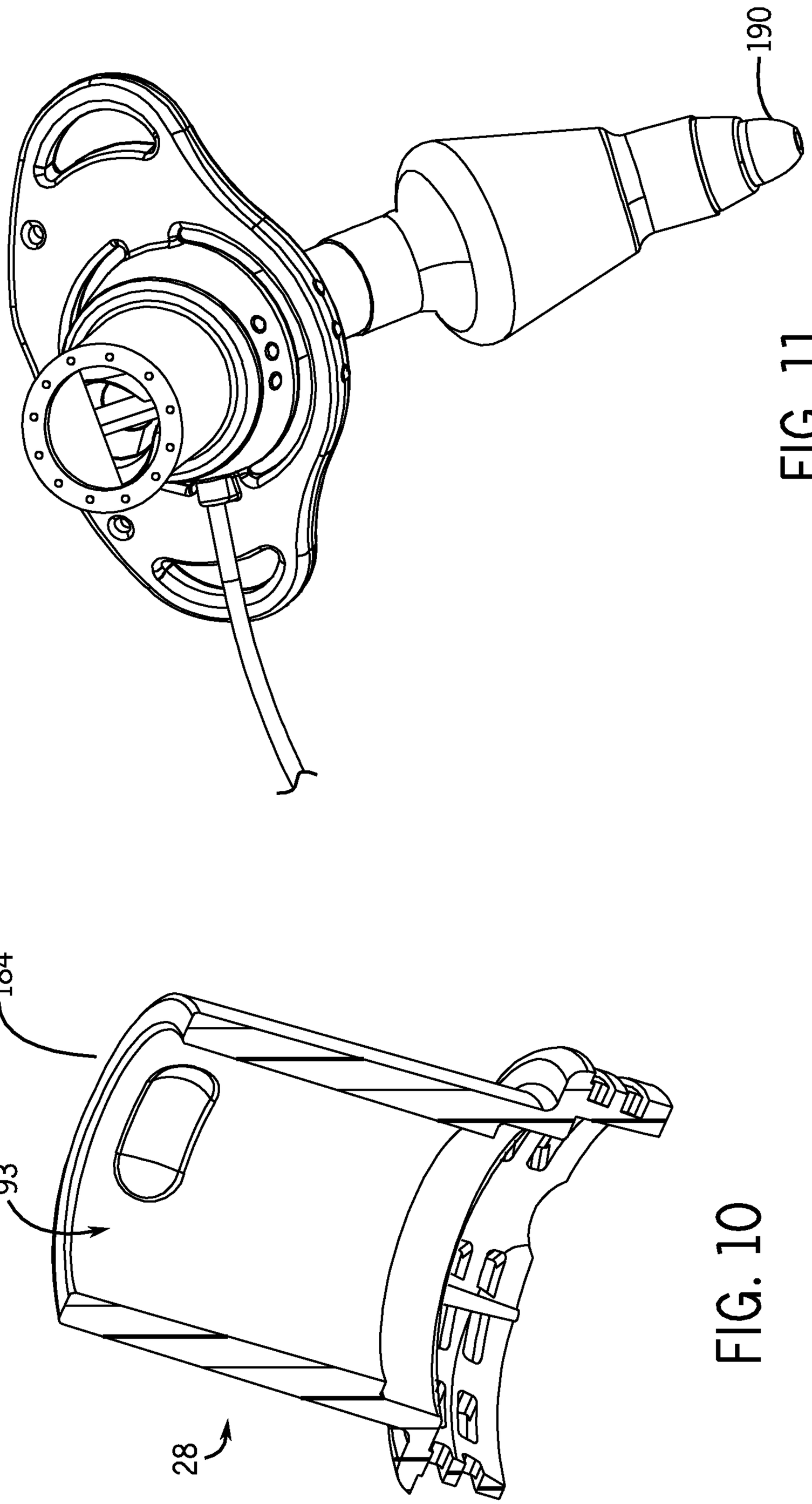
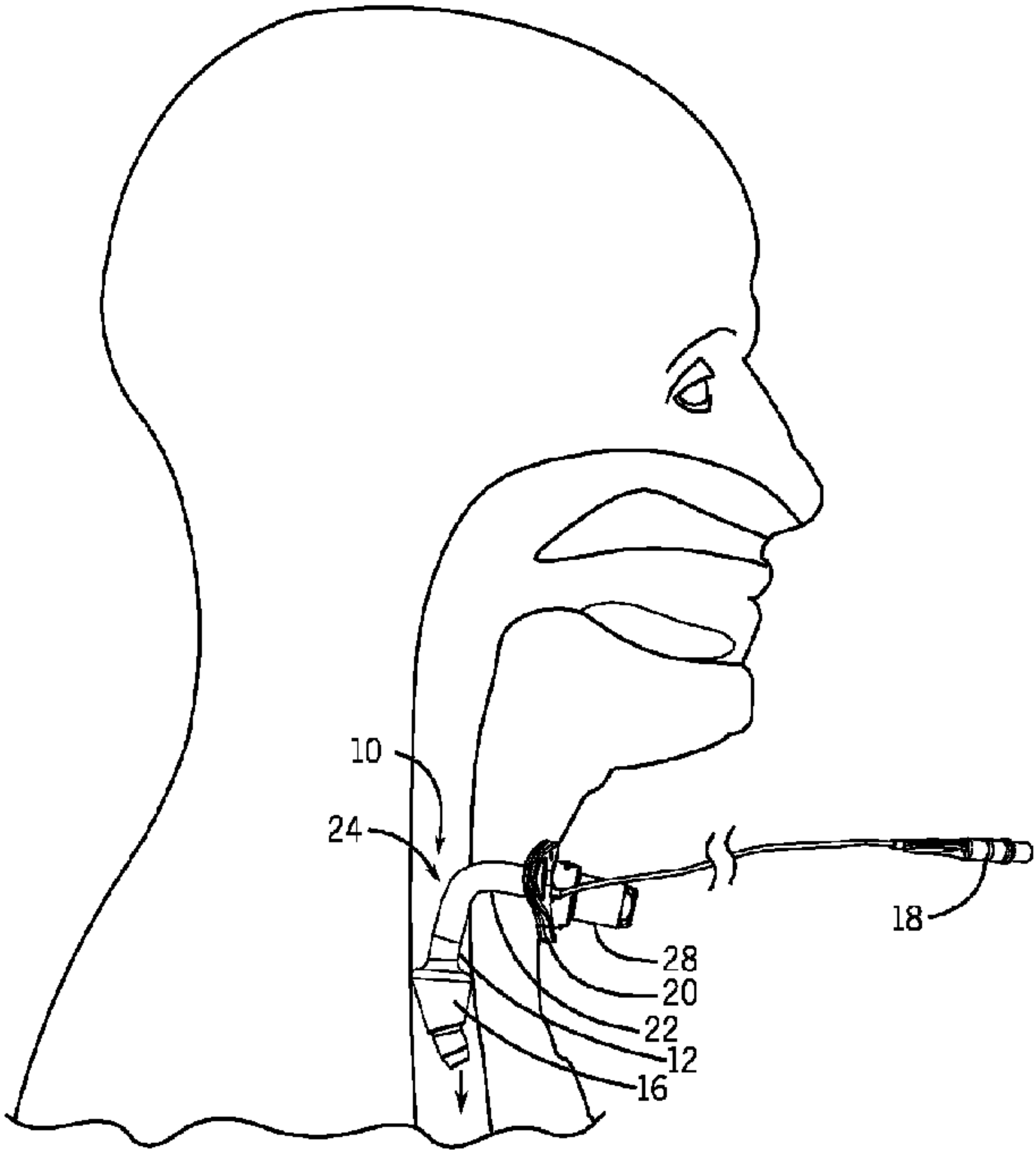


FIG. 11

FIG. 10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