

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2013296521 B2**

(54) Title
Compressible connector for an inner cannula

(51) International Patent Classification(s)
A61M 16/04 (2006.01)

(21) Application No: **2013296521**

(22) Date of Filing: **2013.07.31**

(87) WIPO No: **WO14/022479**

(30) Priority Data

(31) Number
13/565,273

(32) Date
2012.08.02

(33) Country
US

(43) Publication Date: **2014.02.06**

(44) Accepted Journal Date: **2015.11.12**

(71) Applicant(s)
Covidien LP

(72) Inventor(s)
Bruggeman, Martin;Ryan, James;Kiernan, Declan;Finneran, Alan

(74) Agent / Attorney
Pizzseys, PO Box 291, WODEN, ACT, 2606

(56) Related Art
US 4817598



(51) International Patent Classification:
A61M 16/04 (2006.01)

(21) International Application Number:
PCT/US2013/052867

(22) International Filing Date:
31 July 2013 (31.07.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/565,273 2 August 2012 (02.08.2012) US

(71) Applicant: **COVIDIEN LP** [US/US]; 15 Hampshire
Street, Mansfield, Massachusetts 02048 (US).

(72) Inventors: **BRUGGEMAN, Martin**; 79 The Island,
Chapelizod, Dublin 20 (IE). **RYAN, James**; 40 Gallymore
Close, Drimnagh, Dublin 12 (IE). **KIERNAN, Declan**;
Kilmore Dring, Co. Longford (IE). **FINNERAN, Alan**;
Ballinagar, Tullamore, Co. Longford (IE).

(74) Agents: **ANDERSON, Matthew** et al.; 6135 Gunbarrel
Avenue, Boulder, Colorado 80301 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC,
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))

(54) Title: COMPRESSIBLE CONNECTOR FOR AN INNER CANNULA

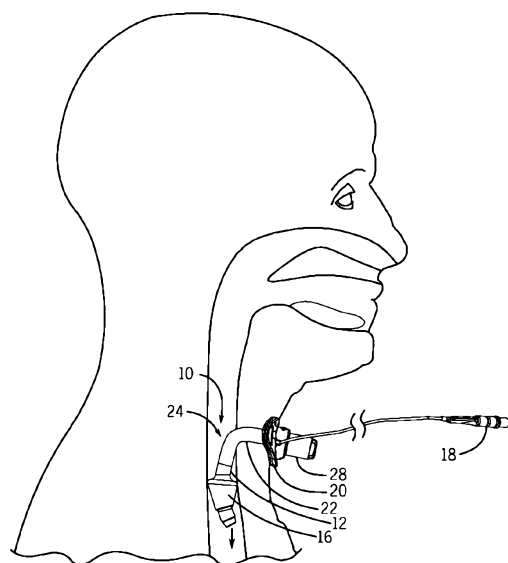


FIG. 1

(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.

COMPRESSIBLE CONNECTOR FOR AN INNER CANNULA

BACKGROUND

5 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
10 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.

15 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
20 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.

25 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
30 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.

- 5 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
10 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
15 ease of placement and connection of the inner cannula during ventilation.

BRIEF DESCRIPTION

This disclosure provides 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
5 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
10 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,
15 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.

20 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
25 medical tubing, such as ventilator tubing.

Thus, in accordance with a first aspect, a tracheal tube assembly includes an outer cannula configured to be positioned in a patient airway. The assembly further includes a flange member secured about the outer cannula and an outer cannula connector coupled to
30 a proximal end of the outer cannula. The assembly further includes an inner cannula configured to be disposed inside the outer cannula such that the inner cannula and the outer cannula are coaxial. The inner cannula features a compressible proximal region that is configured to be positioned inside the outer cannula connector. The compressible proximal

region is capable of assuming a compressed configuration and an uncompressed configuration. The compressed configuration is assumed when the compressible proximal end region is positioned in the outer cannula connector, and the uncompressed configuration is assumed when the compressible proximal end region and not subjected to
5 any biasing forces.

In accordance with another aspect, a tracheal tube inner cannula includes 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
10 configured to be inserted in an outer cannula connector. The flared proximal region includes 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
15 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
20 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
25 first ear and a second ear separated by opposing gaps 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
30 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.

5

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:

10 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;

15

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
20 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;

25 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

30

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

5

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

10 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
15 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.

20

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
25 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
30 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, inasmuch 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.

15

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.

5 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
10 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
15 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
20 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
25 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.

30

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
5 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
10 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
15 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.
20 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
25 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
30 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.

5 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
10 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
15 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
20 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
25 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
30 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-most 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.

5 In one embodiment, a mold or mold form may be used to manufacture the inner cannula 30. 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

10 (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

15 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

20 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.

What is claimed is:

1. A tracheal tube assembly 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;

an inner cannula configured to be disposed inside the outer cannula such that the inner cannula and the outer cannula are coaxial, wherein the inner cannula comprises a compressible proximal region that is configured to be positioned inside the outer cannula connector and wherein the compressible proximal region has a compressed configuration comprising a first diameter when positioned in the outer cannula connector and an uncompressed configuration comprising a second diameter when the compressible proximal region is unbiased and outside of the outer cannula connector wherein the second diameter is larger than a largest outer diameter of the outer cannula connector.

2. The assembly of claim 1, wherein the compressible proximal region of the inner cannula comprises a lip configured to be outside of the outer cannula connector when the inner cannula is inserted.

3. The assembly of claim 2, wherein the lip comprises a largest diameter smaller than the largest outer diameter of the outer cannula connector when the inner cannula is inserted into the outer cannula connector.

4. The assembly of claim 2, wherein the lip comprises a partial annulus having at least one slit formed in a wall of a proximal end of the inner cannula.

5. The assembly of claim 2, wherein the at least one opening extends towards a distal end of the inner cannula and terminates at a location on the inner cannula that is positioned inside the outer cannula connector when the inner cannula is inserted.

6. The assembly of claim 1, wherein the second diameter is larger than 15 mm.
7. The assembly of claim 1, wherein the compressible proximal region is configured to compress such that a gap or opening formed in a wall of a proximal end of the compressible proximal region is smaller in the compressed configuration.
8. The assembly of claim 1, wherein the compressible proximal end comprises a pinch grip.
9. 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.
10. The tracheal tube inner cannula of claim 9, 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.
11. The tracheal tube inner cannula of claim 10, wherein the first protrusion and the second protrusion correspond with lateral sides of the inner cannula when the inner cannula is positioned in a patient.

12. The tracheal tube inner cannula of claim 10, wherein the first protrusion and the second protrusion protrude at least 1 mm from an outer surface of the inner cannula.

13. The tracheal tube inner cannula of claim 9, wherein the opposing notches correspond with a ventral side and a dorsal side of the inner cannula when the inner cannula is positioned in a patient.

14. The tracheal tube inner cannula of claim 9, 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.

15. The tracheal tube inner cannula of claim 14, wherein the lip extends at least partially down a U-shape formed by the opposing notches.

16. 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 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 gaps 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.

17. The assembly kit of claim 16, 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.

18. The assembly kit of claim 17, 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.

19. The assembly kit of claim 18, 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.

20. The assembly kit of claim 18, comprising an obturator.

21. The assembly kit of claim 16, 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.

22. The assembly kit of claim 16, wherein opposing notches terminate within the interior of the outer cannula connector.

23. A tracheal tube assembly 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;

an inner cannula configured to be disposed inside the outer cannula such that the inner cannula and the outer cannula are coaxial, wherein the inner cannula comprises a compressible proximal region that is configured to be positioned inside the outer cannula connector and wherein the compressible proximal region has a compressed configuration comprising a first diameter when positioned in the outer cannula connector and an uncompressed configuration comprising a second diameter when the compressible proximal region is unbiased and outside of the outer cannula connector, wherein the compressible proximal region of the inner cannula comprises a lip configured to be outside of the outer cannula connector when the inner cannula is inserted and wherein the lip comprises a partial annulus having at least one slit formed in a wall of a proximal end of the inner cannula.

1 / 9

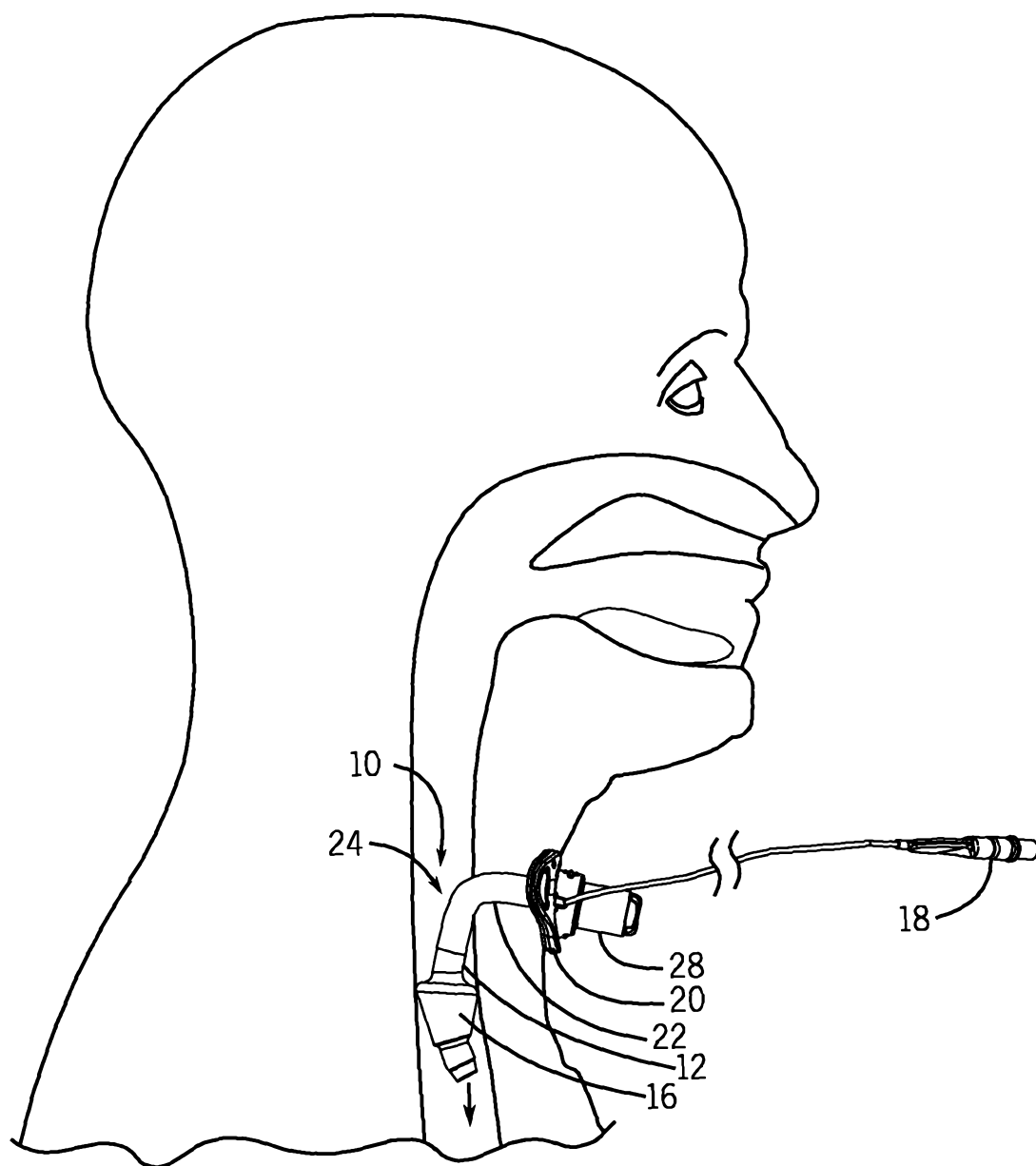
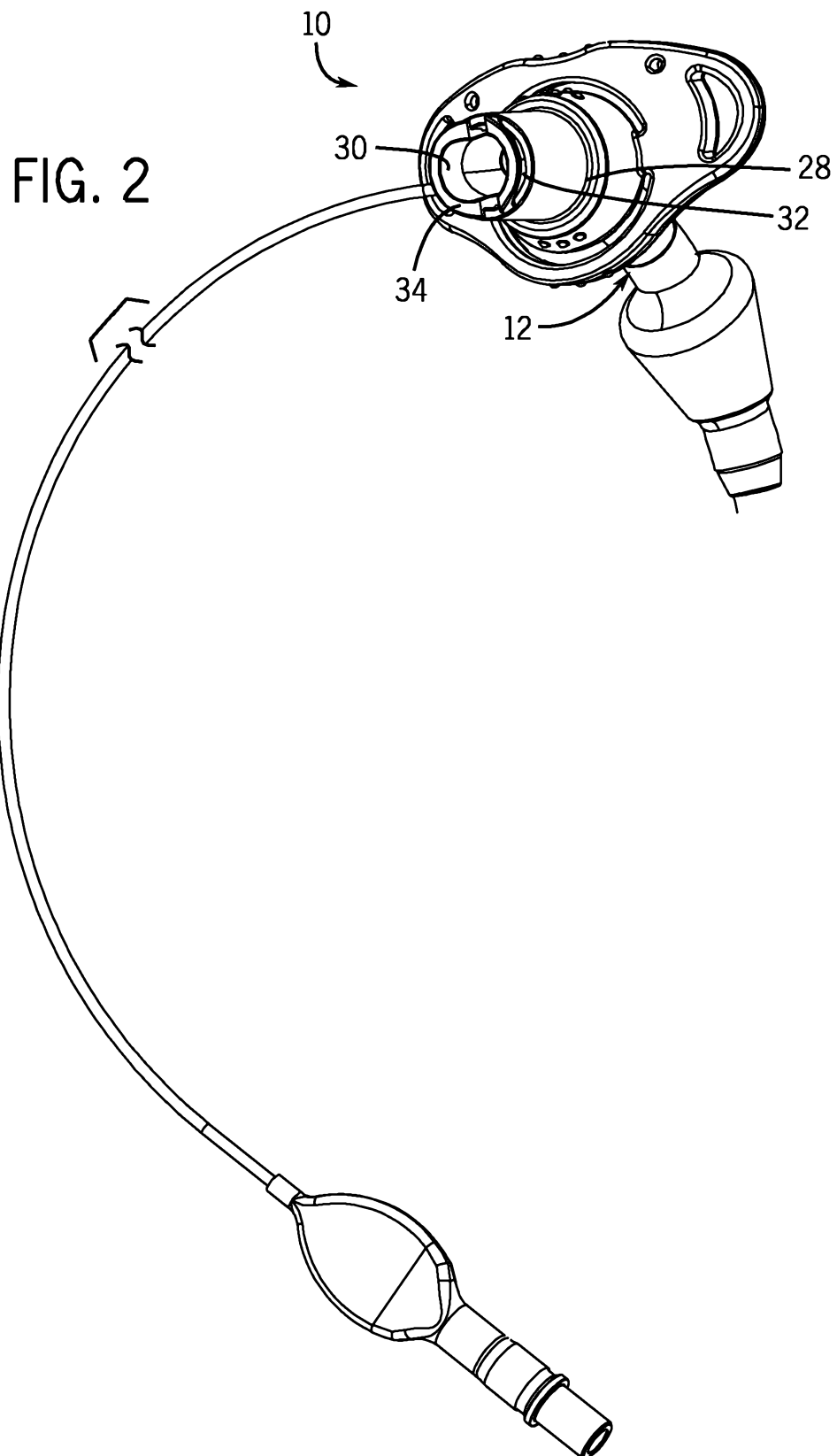


FIG. 1

2 / 9



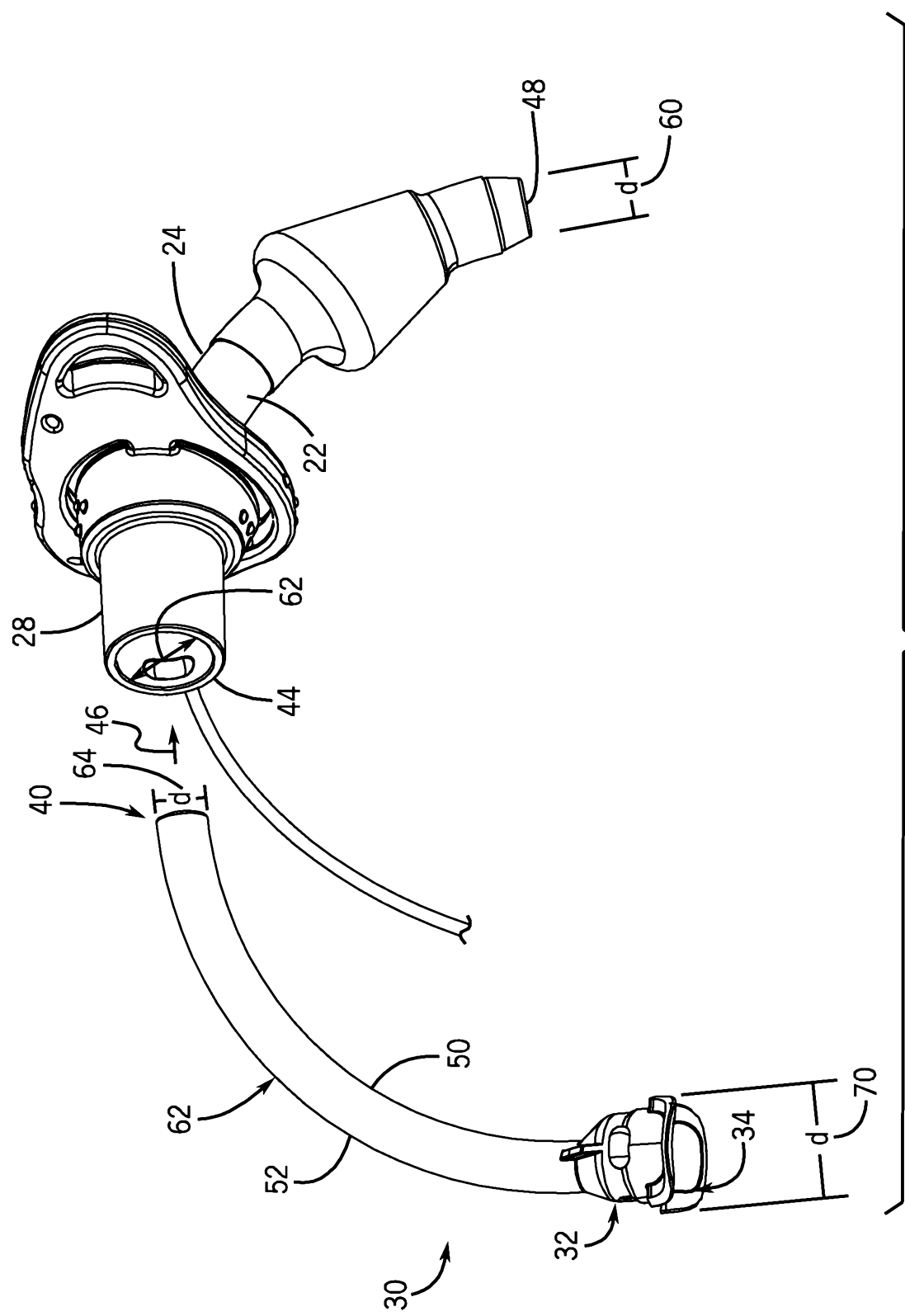


FIG. 3

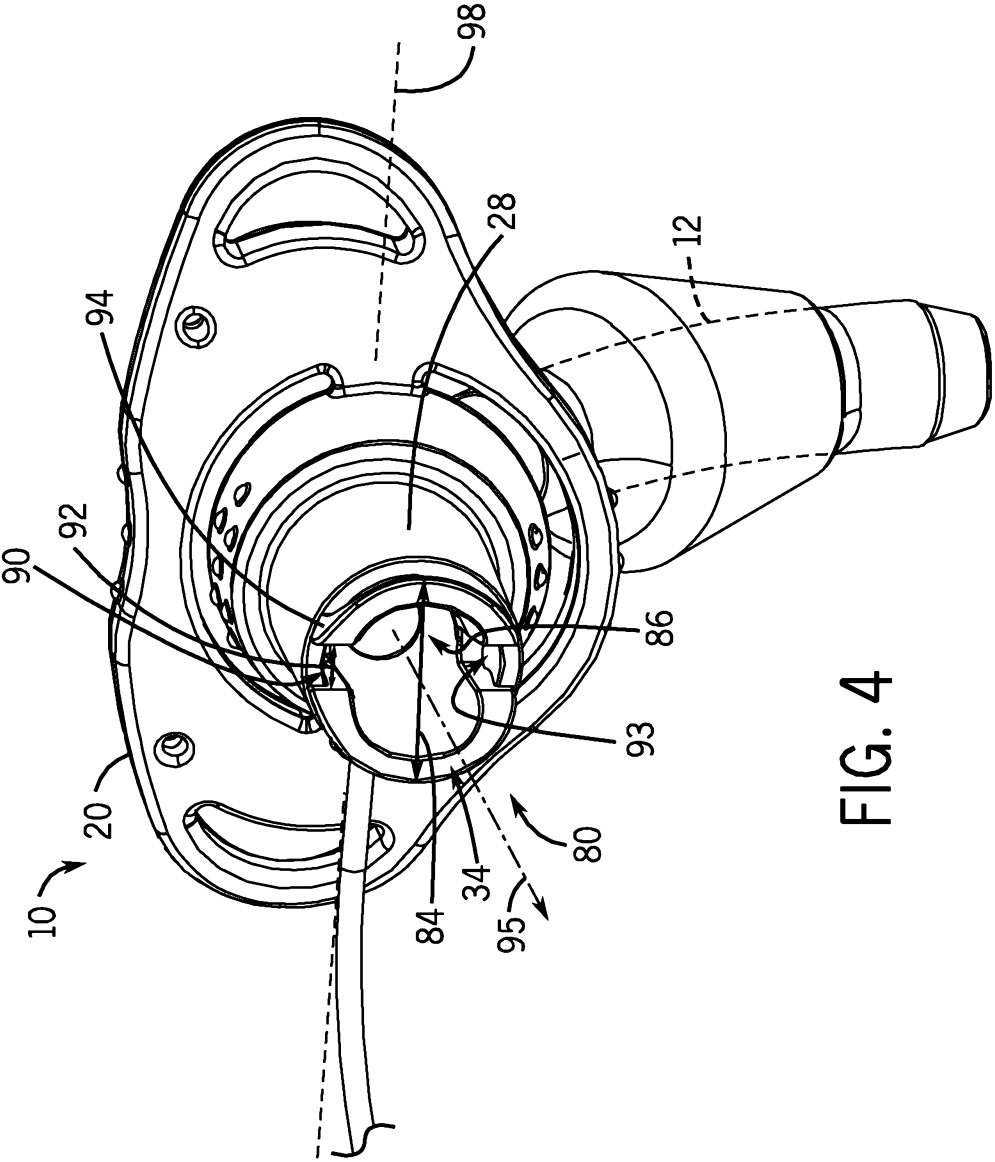


FIG. 4

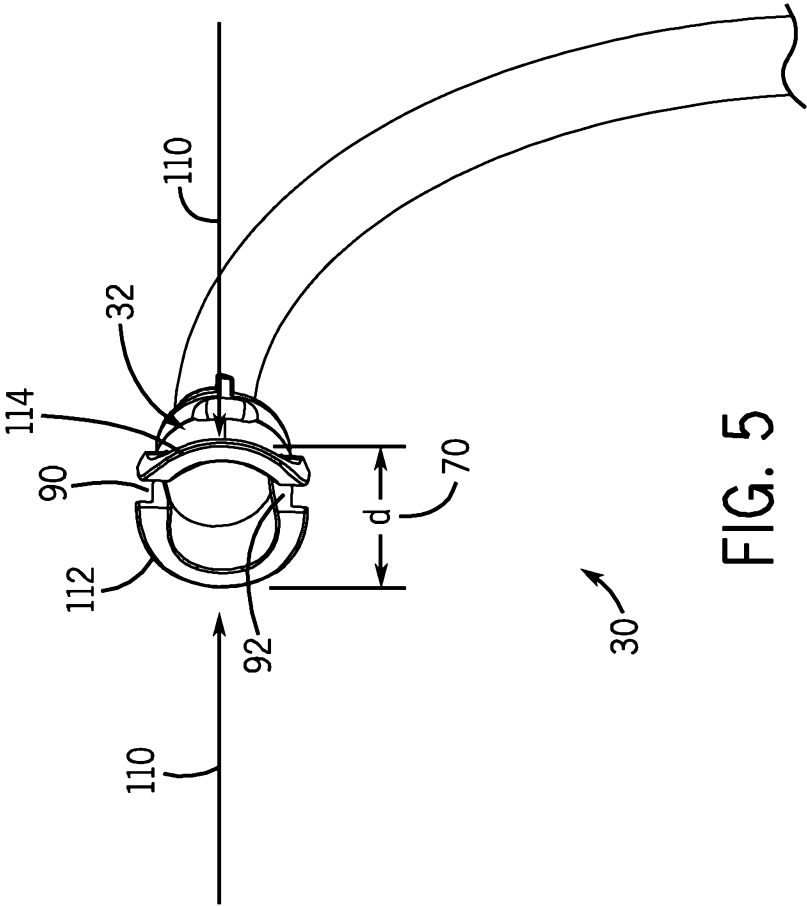


FIG. 5

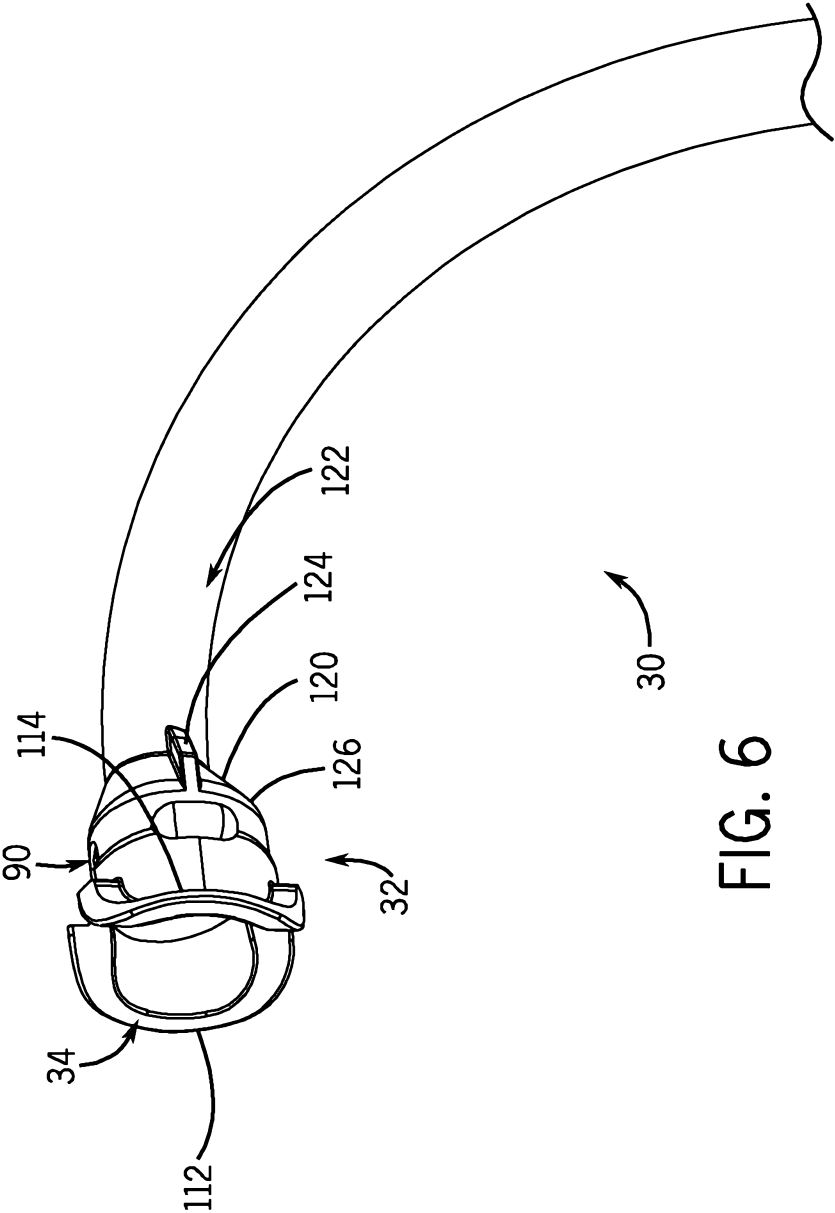


FIG. 6

7 / 9

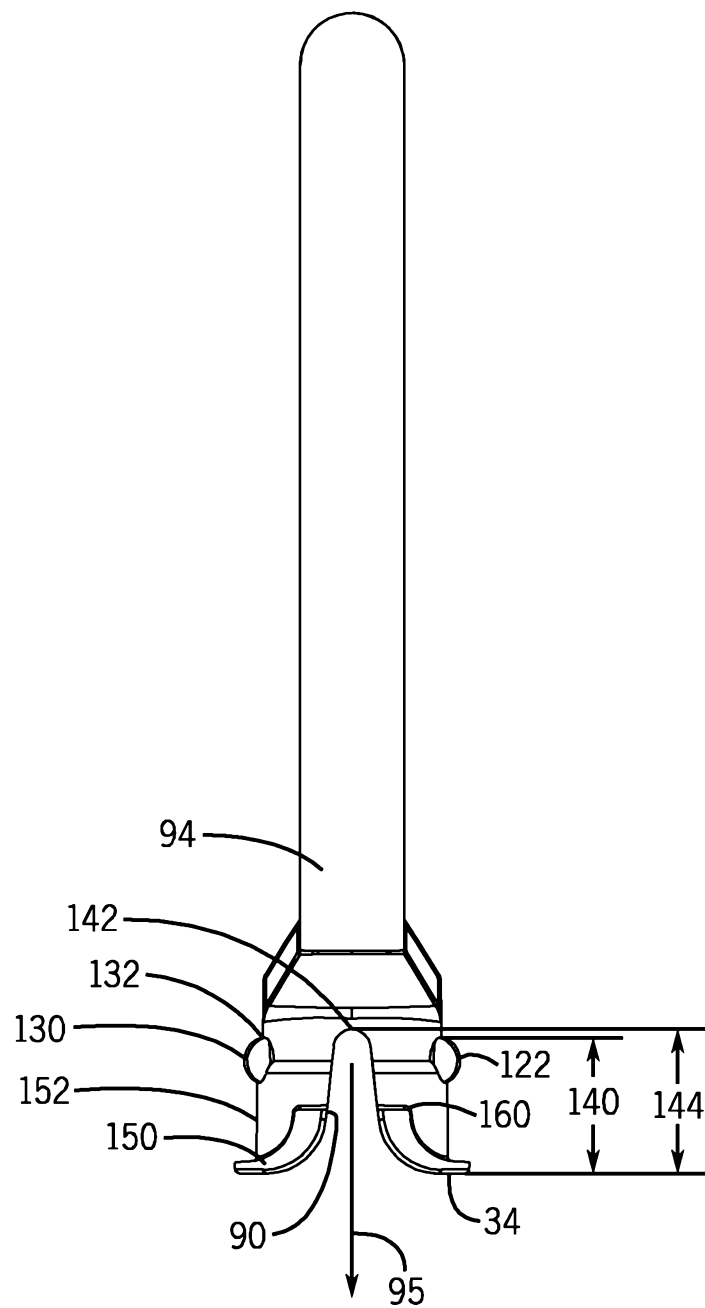
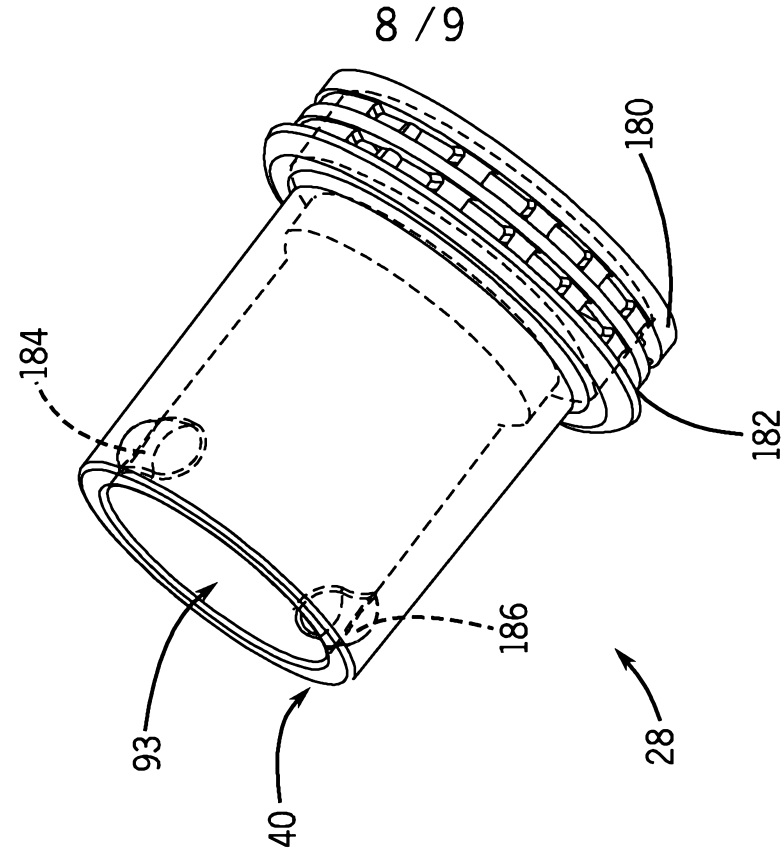
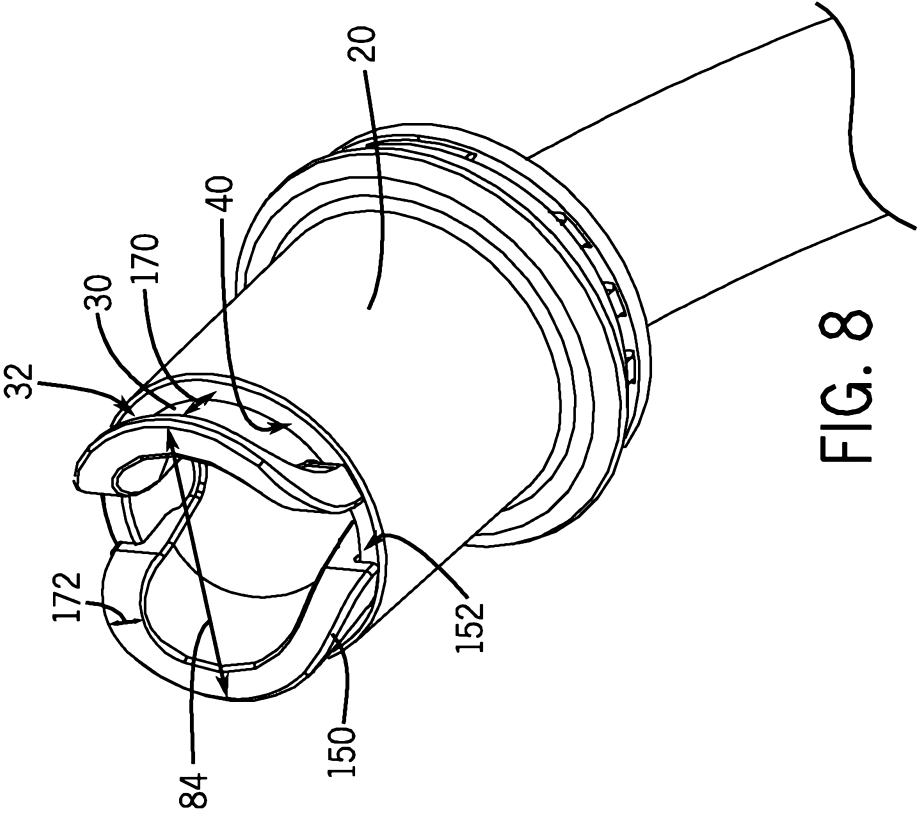


FIG. 7



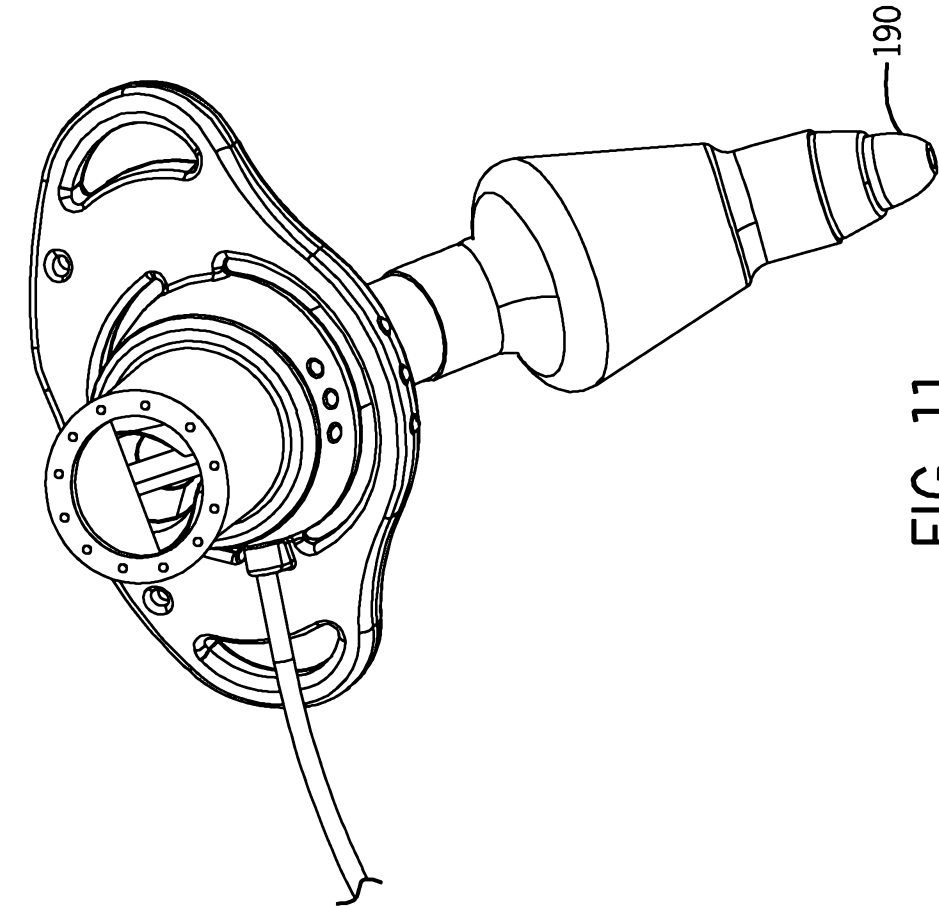


FIG. 11

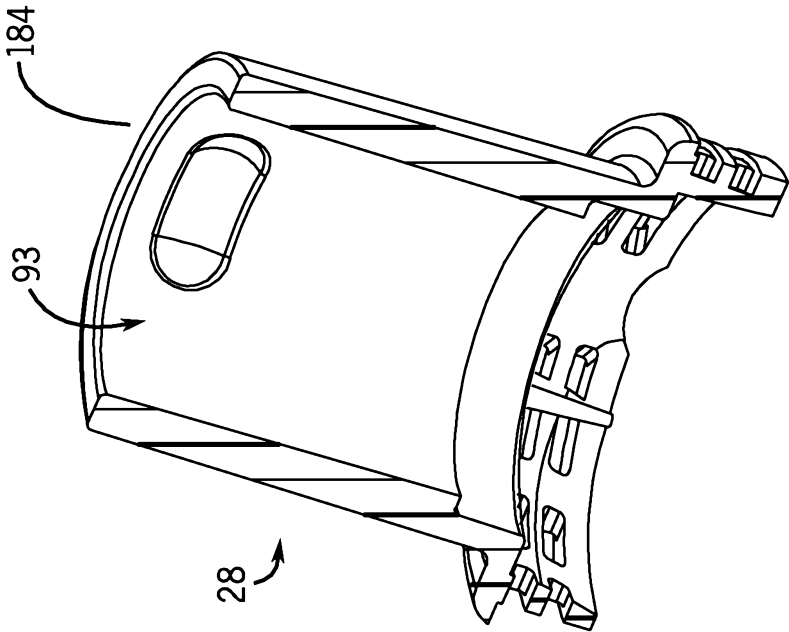


FIG. 10