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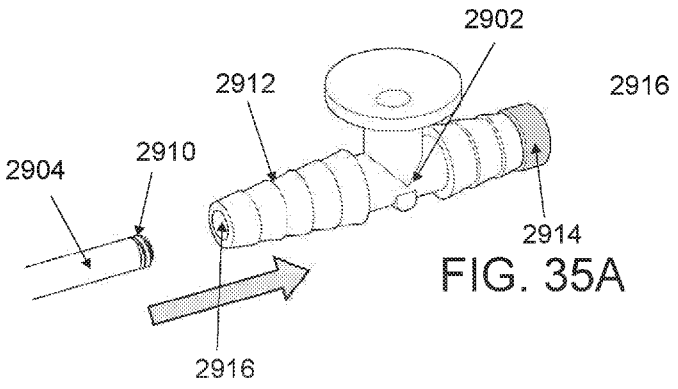

FIG. 35A

(57) Abstract: Described here are devices, systems, kits, and methods for positioning a suction catheter in the airway of a patient. The kit includes a suction catheter a suction connector configured to attach or releasably attach to the suction catheter, and a delivery' device configured to deliver the suction catheter along an endotracheal tube to a suction location. After positioning the tip of the suction catheter at the suction location, the delivery device is removed and the suction connector is attached to the catheter.

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SUCTION CATHETER WITH DETACHABLE CONNECTOR AND METHODS THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application Ser. No. 62/327,059, entitled "Suction Catheter with Detachable Connector and Methods Thereof", filed on April 25, 2016, which is hereby incorporated by reference in its entirety.

FIELD

[0002] The present invention relates to systems, devices, kits, and methods for introducing suction catheters into the airways of patients who are intubated.

BACKGROUND

[0003] Patients who are intubated with an endotracheal (ET) tube are typically intubated to provide acute or chronic treatment with mechanical ventilation, but intubation is also associated with an increase in morbidity. Because ET tubes generally utilize an inflatable balloon or seal between the tube and the walls of the trachea to prevent aspiration or passage of fluids and debris into the trachea, small pools of pathogen-containing secretions may pool in the region above the inflatable balloon, which is typically the subglottic space. If the balloon forms an incomplete seal, small channels may develop between the balloon walls and the walls of the trachea through which debris and subglottic secretions pass into the lower respiratory tract.

[0004] In some instances, a suction catheter may be positioned to clear this debris or secretions via suction. Due to limited space in the airway of an intubated patient, these suction catheters tend to be small in diameter and as a result, very flexible. This flexibility may make the suction catheter difficult to manipulate, which may limit the ability of a practitioner to be able to position the suction catheter at a desired location within the airway.

BRIEF SUMMARY

[0005] Accordingly, there exists a need for devices and methods which allow for rapid deployment of a suction catheter in a patient and which may also be used in conjunction with conventional ET tubes which are already in wide use. Described here are devices, systems, and

methods for providing suction to an airway of a patient. In some variations, the system may comprise a suction catheter and a delivery device. In some variations, the delivery device may comprise an elongate shaft comprising a central shaft region and an atraumatic distal end, an elongate passageway or lumen configured to receive a suction catheter, and a retention element configured to releasably couple to an endotracheal tube. In some variations, the elongate shaft further comprises a grooved piece and a lid piece that are releasably connected to define the elongate passageway. The suction catheter may be at least partially positioned in the elongate passageway and disconnection of the lid piece from the groove piece may release the suction catheter from the elongate passageway. In some variations, the lid piece may be slidably attached to the grooved piece. In some variations, the system may further comprise a stylet positioned in a lumen of the suction catheter. In some variations, the delivery device may further comprise more than one retention element configured to releasably connect the delivery device to an endotracheal tube. Additionally or alternatively, the delivery device may comprise a pair of wings configured to engage an endotracheal tube. In some variations, the delivery device may be curved. In some of these variations, the delivery device may further comprise at least one retention element that may extend away from a center of curvature of the delivery device. In some variations, the delivery device may comprise a skirt member or bulbous structure at an atraumatic distal end of the delivery device.

[0006] Also described here are methods of positioning a suction catheter in an airway of a patient intubated with an endotracheal tube. In some variations, the method may comprise advancing a delivery device into the airway, where the delivery device may comprise an elongate shaft, an elongate passageway, and a retention element. The distal outlet of the elongate passageway of the delivery device may be positioned at or near the vocal cords, and a distal portion of the suction catheter may be advanced out of the distal outlet to advance the distal portion of the suction catheter into a trachea. In variations of the method where the elongate shaft comprises a releasably attached grooved piece and lid piece, the lid piece may be disconnected from the grooved piece to release the suction catheter from the elongate passageway. The suction catheter may be used to apply suction to the trachea. In some variations, advancing a distal portion of the suction catheter may comprise advancing the suction catheter with a stylet positioned in the suction catheter.

[0007] In some variations, positioning the distal outlet of the elongate passageway of the delivery device at or near the vocal cords may comprise positioning the distal outlet within 2 cm of the vocal cords. In some of these variations, positioning the distal outlet of the elongate passageway of the delivery device at or near the vocal cords may comprise positioning the distal outlet within 1 cm of the vocal cords. Additionally or alternatively, positioning the distal outlet of the elongate passageway of the delivery device at or near the vocal cords may comprise positioning the distal outlet in the trachea distal to the vocal cords. In some variations, the delivery device may comprise a skirt member, and positioning the distal outlet of the elongate passageway of the delivery device at or near the vocal cords may comprise positioning at least a portion of the skirt member in the trachea distal to the vocal cords. In some variations, the lid piece may be slidably connected to the grooved piece, and disconnecting the lid piece from the grooved piece may comprise proximally sliding the lid piece relative to the grooved piece. Additionally or alternatively, the delivery device may comprise a retention element, and the method may further comprise slidably connecting the delivery device to the endotracheal tube with the retention element.

[0008] In some variations, the suction catheter may comprise of a shaft and a connector. In some variations, the suction catheter shaft may be reinforcement along the proximal and central regions. In some variations, the suction catheter connector may be removable and/or reattachable.

[0009] Also described here are devices, systems, kits, and methods for positioning a suction catheter in the airway of a patient. The kit includes a suction catheter a suction connector configured to attach or releasably attach to the suction catheter, and a delivery device configured to deliver the suction catheter along an endotracheal tube to a suction location. After positioning the tip of the suction catheter at the suction location, the delivery device may be removed and the suction connector may be attached to the catheter.

[0010] In one embodiment, a method of providing suction to an airway of a patient may be provided, comprising placing a suction guide device along an endotracheal tube inserted into an airway of a patient, wherein the endotracheal tube comprises a distal end and a proximal end, advancing the suction guide along the endotracheal tube towards the distal end of the endotracheal tube, positioning a catheter shaft at a location using the suction guide, withdrawing

the suction guide from the airway while maintaining the catheter shaft at the location, and attaching a suction connector to the catheter shaft after withdrawing the delivery device from the airway. The suction connector may be pre-attached to the catheter shaft and the method further may comprises removing the suction connector from the catheter shaft before withdrawing the suction guide from the airway. The method may further comprise securing the catheter shaft to the endotracheal tube to resist displacement of the catheter shaft from the location after withdrawing the suction guide from the airway. Securing the catheter shaft may comprise coupling the suction catheter and endotracheal tube using a coupling member. The coupling member may be a clip, clamp or adhesive tape. The suction connector may be pre-attached to the catheter shaft at a first end of the suction connector. Attaching the suction connector to the catheter shaft may be performed using a second end of the suction connector. Inserting the suction catheter may be performed before advancing the delivery device along the endotracheal tube, or may be performed after advancing the delivery device along the endotracheal tube. The suction catheter may be pre-inserted into the lumen of the delivery device at the point of manufacture.

[0011] In another embodiment, a system comprises a suction guide configured to slidably couple to an endotracheal tube, a catheter shaft configured to couple to the suction guide, and a suction connector comprising a first end, a second end and a lumen therebetween, wherein the suction connector may be configured to attach to the catheter shaft, wherein the suction guide, catheter shaft and suction connector are located in a sealed packaging. The system may further comprise one or more coupling members. The one or more coupling members may be a clip, clamp, or adhesive tape. The suction connector may be configured to releasably attach to the catheter shaft. The suction connector may be pre-attached to the catheter shaft in the packaging. The catheter shaft may be pre-inserted into the suction guide in the packaging.

[0012] In still another embodiment, a system comprises a catheter shaft comprising a proximal end, a distal end, and a longitudinal lumen therebetween, and a suction connector comprising a first end, a second end and a lumen therebetween, wherein the suction connector may be configured to be attachable to the catheter shaft at the first end and the second end of the suction connector. The first end of the suction connector may have a different configuration than the second end of the suction connector. The second end may comprise a metal and the first end does not comprise a metal. The catheter shaft may comprise one or more interference openings

spaced apart from a proximal end of the catheter shaft configured to attach to the suction connector. A proximal end of the catheter shaft may comprise a helically threaded interface. The second end of the suction connector may comprise a helically threaded interface complementary to the helically threaded interface of the catheter shaft. The first end of the suction connector comprises may be sized to form a friction fit with the proximal end of the catheter shaft. The second end of the suction connector comprises a radially inward protrusion within the lumen and in the second end of the suction connector. The radially inward protrusion may comprise a height orthogonal to the lumen, a leading surface and a trailing surface, where the leading surface may be closer to a second opening of the second end than the trailing surface. The leading surface may be angled away from the second opening. The leading surface may comprise a first open angle that may be greater than a second open angle of the trailing surface. The radially inward protrusion comprises a truncated shape, comprising a tip surface between the leading and trailing surfaces, wherein the tip surface comprises an angular orientation that may be different from the leading surface and the trailing surface. The height of the radially inward protrusion may be in a range of about 0.020 inches to about 0.035 inches. The first open angle may be in the range of about 135 degrees to about 165 degrees. The second open angle may be in the range of about 50 degrees to about 90 degrees. The suction catheter may further comprise a suction control opening in communication with the lumen. The suction catheter may further comprise a closure structure configured to reversibly close communication through the suction control opening and into the lumen. The closure structure may comprise a tethered cap. The system may further comprising a suction guide comprising a lumen and configured to slidably couple to an endotracheal tube, wherein the lumen may be configured to removably receive the catheter shaft. The suction guide, catheter shaft, and suction connector may be provided in sealed packaging. The catheter shaft may further comprise a tongue reinforcement member, the tongue reinforcement member comprising a proximal end, a distal end and a elongate body therebetween. The proximal end of the catheter shaft may comprise a threaded metal annular body, and the proximal end of the tongue reinforcement member may be attached to threaded metal annular body. The distal end of the tongue reinforcement member may be located in the longitudinal lumen of the catheter shaft and may be unattached to the catheter shaft. The distal end of the tongue reinforcement member may be located 2 cm to 10 cm proximal to the distal end of the catheter shaft. The system may further comprise a suction guide configured to releasably and slidably couple to an endotracheal tube, and comprising an

elongate lumen configured to receive the catheter shaft. The tongue reinforcement member may be a metal wire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 depicts the anatomy of the upper airway of a patient.

[0014] FIGS. 2A and 2B depict perspective views of a variation of a delivery device described here.

[0015] FIGS. 3A and 3B depict perspective views of a variation of a delivery device described here. FIGS. 3C and 3D depict cross-sectional front views of the delivery device of FIGS. 3A and 3B. FIG. 3E shows a perspective view of the delivery device of FIGS. 3A and 3B.

[0016] FIGS. 4A, 4B, 4C, and 4D – FIGS. 17A, 17B, 17C, and 17D depict top, side, front, and perspective views, respectively, of variations of distal portions of the delivery devices described here.

[0017] FIGS. 18A, 18B, 18C, and 18D – FIGS. 24A, 24B, 24C, and 24D depict top, side, front, and perspective views, respectively, of variations of distal portions of the delivery devices described here that comprise more than one material.

[0018] FIGS. 25A and 25B depict perspective views of variations of distal portions of the delivery devices as described here.

[0019] FIG. 26A depicts a perspective view of the proximal portion of the delivery device of FIGS. 2A and 2B. FIG. 26B depicts a front view of the proximal portion of the delivery device of FIGS. 2A and 2B.

[0020] FIGS. 27A and 27B depict perspective views of a variation of a delivery device described here.

[0021] FIGS. 28A and 28B depict a suction catheter with suction connector in an attached and detached configuration, respectively. FIGS. 28C and 28D schematically depict the suction catheter with a reinforcement member, in a straight and curved configuration, respectively.

[0022] FIG. 29 depicts an exemplary sealed kit or package comprising a suction catheter with a detachable hub and a suction catheter guide.

[0023] FIG. 30A is a side view of a suction connector; FIG. 30B is side cross-sectional view of the suction connector; and FIG. 30C is detailed view of the coupling structure in FIG. 30B.

[0024] FIG. 31A is side view of the suction connector coupled to the catheter shaft; FIG. 31B is a side cross-section view of FIG. 31A.

[0025] FIG.32 is a perspective view of the distal tip of the suction line inserted into the suction guide.

[0026] FIGS. 33A and 33B are perspective views of the suction guide and suction line in an unlocked and locked configuration, respectively.

[0027] FIG. 34 is a perspective view of the suction guide positioned against an endotracheal tube.

[0028] FIG. 35A depicts the detachment of the catheter shaft and the suction connector; FIG. 35B depicts the reattachment of the catheter shaft and the suction connector.

[0029] FIG. 36A is a schematic cross-sectional view of a patient and the alignment of the positioning of the suction guide against the opening of the oropharynx; FIG. 36B and 36C are schematic cross-sectional views of the partial and complete withdrawal of the suction guide from the patient, respectively.

DETAILED DESCRIPTION

Device Overview

[0030] Described here are delivery devices, systems, and methods for positioning a suction catheter in a patient's airway. Specifically, a distal end of the suction catheter may be positioned in the subglottic space of a patient, such that the suction catheter may be used to remove debris or secretions from the trachea. For example, a patient may be intubated with an endotracheal ("ET") tube, and the devices described here may advance a suction catheter along the ET tube to position the suction catheter in the patient's airway proximal to a balloon of the ET tube.

Continuous or intermittent suctioning with the suction catheter may help prevent microaspiration or aspiration of material and/or bacteria past the balloon of the ET tube and into the patient's lungs.

[0031] The systems described here generally comprise a suction catheter and a delivery device. The delivery device may be configured to engage the suction catheter such that advancement of the delivery device into the airway of a patient also advances the suction catheter. The delivery device may facilitate placement of a distal end of the suction catheter in the space between the ET balloon and the vocal cords of the patient. Once the suction catheter is so positioned, some variations of the delivery device may be configured to disengage the suction catheter to allow for removal of the delivery device while leaving the suction catheter in the airway. Alternatively, the delivery device may be configured such that removal of the delivery device also removes the suction catheter, and the delivery device may remain in place while suctioning occurs.

[0032] For the purposes of illustration, FIG. 1 schematically depicts the anatomy of the upper airway of a patient intubated with an ET tube (100). To position the ET tube (100), the ET tube (100) may be inserted through the mouth (M) of a patient, and may be advanced past the epiglottis (EP) into the trachea (TR), passing through the subglottic space (SG). The ET tube (100) may comprise an ET balloon (102). Generally, the ET balloon (102) may be positioned in the trachea (TR) distal to the vocal cords (VC) in the subglottic space (SG). The ET tube (100) may further comprise an ET inflation tube (104) coupled to the ET balloon (102) and fluidly coupling the ET balloon (102) to an ET inflation port (106). Gas or fluid may be inserted into the ET balloon (102) through the ET inflation tube (104) and the ET inflation port (106) to inflate the ET balloon (102) in the trachea (TR), and gas or fluid may be withdrawn from the ET balloon (102) through the ET inflation tube (104) and the ET inflation port (106) to deflate the ET balloon (102). For example, a syringe or other fluid reservoir (not shown) may be connected to the ET inflation port (106) to inflate or deflate the ET balloon (102).

[0033] FIGS. 2A and 2B are perspective views of a variation of a delivery device (200) described here. The delivery device may comprise an elongate shaft (202), one or more handles (204), an atraumatic distal end (206), and one or more retention elements (208, 209) or clamps. The elongate shaft may comprise an elongate passageway or lumen extending between a

proximal insertion inlet (210) and a distal outlet (212). The elongate passageway or lumen may be integrally formed with the elongate shaft (202), or may be attached in some manner. A suction catheter (not pictured) may be inserted into the proximal insertion inlet (210) and advanced to extend distal to the distal outlet (212), which may allow suctioning of a desired location in an airway (e.g., the subglottic space (SG)) when the delivery device is inserted into an airway. The delivery device may also have one or more handles. In some examples, one or more handles may facilitate manipulation and control of the delivery device by a user. The delivery device in FIGS. 2A and 2B comprises one handle (204), which comprises a lock (214) to releasably secure a suction catheter to the elongate shaft lumen. The handle may engage or contact a portion of a patient (e.g., a patient's teeth) when the delivery device is advanced and the handle may be shaped or constructed from a material or materials that decrease the risk of trauma to that portion of a patient. For example, the handle may comprise one or more rounded or bulbous structures and/or may comprise one or more compliant materials (e.g., rubber, soft silicon). The delivery device may comprise an atraumatic distal end or distal tip (206) that may be the portion of the delivery device advanced most distally into an airway. The atraumatic distal end may be shaped (e.g. comprise rounded or bulbous structures) or constructed from a material (e.g., soft silicone, santoprene or polyurethane) or materials that reduce the risk of trauma to a patient's tissue (e.g., vocal cords). The delivery device in FIGS. 2A-2B comprises retention elements (208, 209) which may be used for connecting or aligning the delivery device to an ET tube. An elongate shaft, one or more handles, an atraumatic distal end, and/or one or more retention elements may be configured to indicate proper placement of a delivery device on an ET tube and/or a desired distance of advancement into an airway, as will be discussed in more detail herein.

[0034] FIGS. 3A-3E show a variation of a delivery device (300) that may disengage from a suction catheter after the delivery device and the suction catheter have been inserted into an airway. In this case, an elongate shaft may comprise a grooved piece and lid piece that are releasably attached. This may allow the delivery device to be removed from the airway while the suction catheter remains in a desired location where it was delivered (e.g., the subglottic space). As shown in FIG. 3A-3E, the delivery device (300) may comprise a grooved piece (302), a lid piece (304), and one or more retention elements (306) for connecting or aligning the delivery device to an ET tube. The lid piece (304) and grooved piece (302) may be releasably connected

to define an elongate passageway or lumen (308) having a proximal insertion inlet (310) and a distal outlet (312). It should be appreciated that some variations of the delivery device may not comprise a lid piece, but may still be configured to disengage from a suction catheter in an airway. The delivery device may comprise a first handle (303) connected to the grooved piece and the second handle (305) connected to the lid piece, each of which may be manipulated to manipulate the grooved piece (302) and the lid piece (304), respectively. The lumen (308) is generally configured to receive a portion of a suction catheter to temporarily hold the suction catheter within the delivery device (300). For example, FIG. 3B shows the delivery device (300) of FIG. 3A with a suction catheter (314) positioned in the lumen. As shown there, the suction catheter (314) may comprise a suction port (316) at a proximal end of the suction catheter (314). The suction port (316) may allow for connection of the suction catheter (314) to a suction source (not shown), which may provide suction to the suction catheter (314). Also shown in FIG. 3B is a stylet (318), which may optionally be positioned in the suction catheter (314) to aid in advancement of the suction catheter (314), as will be discussed in more detail herein, or may be initially inserted into the lumen (308) of the delivery device and later swapped out for the suction catheter (314).

[0035] When the suction catheter (314) is positioned in the lumen of the delivery device, such as shown in FIG. 3B, a proximal portion of the suction catheter may extend into the lumen (not pictured) through the proximal insertion inlet (310). Similarly, a distal end of the suction catheter (314) may extend out of the distal outlet (312) of the lumen. In some instances, a distal end of the suction catheter (314) may be positioned inside of the lumen. It should be appreciated that the suction catheter (314) may be advanced into the proximal insertion inlet (310) to advance the suction catheter (314) along the lumen (which may advance a distal end of the suction catheter (314) out of the distal outlet (312) and/or may increase the amount of the suction catheter (314) extending from the distal outlet). Similarly, the suction catheter (314) may be withdrawn from the proximal insertion inlet (310) to withdraw the suction catheter (314) along the lumen (308) (which may reduce the amount of the suction catheter (314) extending from the distal outlet and/or withdraw the distal end of the suction catheter (314) into the distal outlet (312)).

Elongate Shaft

[0036] The delivery device may be configured to constrain the suction catheter within an elongate passageway or lumen, which may reduce or otherwise limit the bending or buckling of the suction catheter while positioned in the lumen. This may increase column strength or the pushability of the suction catheter, which may facilitate advancement of the suction catheter along the delivery device. Additionally, the suction catheter may conform to the shape of the delivery device when positioned in the lumen, which may facilitate advancement of the suction catheter along an ET tube, as discussed in more detail herein. The lumen of the delivery device may be configured to accommodate a predetermined size (e.g., 10Fr) or sizes of suction catheters. In some variations, the delivery device may have more than one lumen, which may, for example, facilitate the use of more than one catheter (e.g., a suction catheter and an infusion catheter for irrigation).

[0037] In variations of the delivery device that comprise an elongate shaft without a lid, a lumen of the delivery device may be a lumen of the elongate shaft. The shapes of the elongate shaft and lumen transverse cross-sections may be any suitable shape (e.g., circle, oval, rectangle). These shapes may be the same or different for the elongate shaft and lumen, and these shapes may be uniform throughout the length of the elongate shaft, but need not be. In some variations, it may be advantageous for the elongate shaft to have rounded edges in order to reduce the risk of trauma to a patient's tissue. The sides of the elongate shaft may comprise openings or perforations, as is seen in FIGS. 2A and 2B, or the sides of the elongate shaft may be solid, as is seen in FIGS. 3A-3E. Openings or perforations in the elongate shaft may be advantageous (e.g. may allow for visualization of a catheter in the elongate shaft lumen, increase flexibility of the elongate shaft). An elongate shaft may comprise any suitable material or materials (e.g., ABS or pebax) and may comprise one or more components. For example, an elongate shaft may comprise a tubular structure (e.g., pebax tube) and a support structure. The tubular structure may be flexible and comprise the lumen of the delivery device and the support structure may be more rigid than the tubular structure. The support structure may provide a defined shape (e.g., curve) to the elongate shaft and/or may be a connection point for one or more components of the delivery device (e.g., may be connected to the tubular structure, distal tip, retention element). The elongate shaft may be integrally formed with the distal tip, one or more handles, and/or one or more retention elements or may be formed separately. In variations where the elongate shaft is formed separately from other components of the delivery device, the

elongate shaft may be connected to these components in any suitable manner (e.g., via adhesive, ultrasonic bonding, welding, or the like).

[0038] In some variations, as shown in FIGS. 3A-3E, and seen best in FIGS. 3C and 3D, the delivery device may comprise a lid piece (304) that is releasably connected to a grooved piece (302). When the suction catheter (314) is positioned in the airway of a patient, the lid piece (304) may be disconnected from the grooved piece (302) to release the suction catheter (314). In instances where the suction port (316) may be too large to enter the proximal inlet (310) of the lumen (308), it may not be possible to proximally withdraw the delivery device (300) from a patient while the lid piece and grooved piece are connected without also withdrawing the suction catheter (314). Disconnecting the lid piece (304) from the grooved piece (302) may allow the delivery device to release the suction catheter (314) from the delivery device (300) without needing to withdraw or otherwise reposition the suction catheter (314). Specifically, disconnecting the lid piece (304) from the grooved piece (302) may open the lumen (308) to allow the suction catheter (314) to be removed through a side opening (322) in the grooved piece.

[0039] For example, FIG. 3C shows a cross-sectional front view of the delivery device (300). As shown there, the grooved piece (302) may include a channel (320) having a side opening (322). When the lid piece (304) is releasably connected to the grooved piece (302), the lid piece (304) may cover the side opening (322) to define the lumen (308). Accordingly, when a suction catheter (314) is positioned in the lumen (308) as shown in FIG. 3C, the lid piece (304) and grooved piece (302) may encircle the suction catheter (314), which may prevent the suction catheter (314) from exiting through the side opening (322) of the grooved piece (302). When the lid piece (304) is disconnected from the grooved piece (302), as shown in a cross-sectional front view in FIG. 3D, the side opening (322) may be exposed which may allow the suction catheter (314) to exit from the channel (320) through the side opening (322). This may allow the grooved piece (302) to move transversely away from the suction catheter (314) to disengage the delivery device from the suction catheter (314) without requiring axial movement of the suction catheter (314).

[0040] The lid piece (304) and grooved piece (302) may be releasably connected in any suitable manner. In some variations, the delivery device may comprise a peel-away lid piece or

structure, and the lid piece (304) and grooved piece (302) may be held in a fixed relationship via one or more frangible connections. The one or more frangible connections may be broken or otherwise severed to release the lid piece (304) from the grooved piece (302). In some variations, the grooved piece (302) and lid piece (304) may be formed as a single member, where thinned or perforated regions may separate the grooved piece (302) and the lid piece (304). In these variations, the connecting regions may be frangible upon application of a force to the lid piece (304) and/or grooved piece (302). In other variations, the grooved piece (302) and lid piece (304) may be formed separately, and may be connected (e.g., via adhesive, ultrasonic bonding, welding, or the like), where the connections between the grooved piece (302) and lid piece (304) are frangible.

[0041] In other variations, the grooved piece (302) and lid piece (304) may be slidably connected. In these variations, the delivery device (300) may be configured such that the lid piece (304) may be slid relative to the grooved piece (302) to expose the side opening (322) of the grooved piece, as shown in FIG. 3E. Further withdrawal of the lid piece (304) relative to the grooved piece (302) may disconnect the lid piece (304) from the grooved piece (302). The lid piece (304) and the grooved piece (302) may be slidably connected in any suitable manner. In some instances, the grooved piece (302) may comprise one or more tracks, and a portion of the lid piece (304) may be configured to be slidably received within the one or more tracks of the grooved piece (302). Additionally or alternatively, the lid piece (304) may comprise one or more tracks, and a portion of the grooved piece (302) may be configured to be slidably received within the one or more tracks of the lid piece (304).

Atraumatic Distal End

[0042] An atraumatic distal end or distal tip of a delivery device may be advanced into a patient's airway in order to deliver a suction catheter to the subglottic space (distal to the vocal cords and proximal to an ET balloon). When the distal tip of the delivery device has been positioned at a desired location in the airway (e.g., in proximity of the vocal cords), the suction catheter may be advanced relative to the delivery device, such that the distal end of the suction catheter is advanced distal to the distal tip of the delivery device. The distal tip of the delivery device may be advanced distal to the vocal cords and into the subglottic space, but need not be. For example, the distal tip of the delivery device may be advanced to a position proximal to the

vocal cords, and the distal end of the suction catheter may then be advanced relative to the delivery device such that only the suction catheter moves past the vocal cords and into the subglottic space.

[0043] In some variations, it may be advantageous for the distal tip of the delivery device to have a shape and/or materials that reduce the risk of trauma to the vocal cords or other tissue that the distal tip may engage. For example, distal tip may comprise a distal edge and/or lateral protrusions that may be configured to be atraumatic if one or more of these surfaces contacts tissue. The distal edge may be the most distal portion of the distal tip, and may be the portion of the delivery device most likely to contact tissue that is in the longitudinal path of the delivery device as the delivery device is advanced along an ET tube. The distal edge may comprise one or more different shapes, including a blunted shape or a more spherical, bulbous shape. Lateral protrusions may extend in a transverse plane relative to the direction of advancement of the delivery device along an ET tube. These protrusions may be defined as portions of the distal tip that extend in the transverse plane from the delivery device midline a distance greater than twice the diameter of the elongate passageway. Lateral protrusions may comprise one or more sizes and shapes, including a blunted shape and a more spherical, bulbous shape. The way in which the distal tip may contact tissue may relate to the relationship between the distal tip and a retention element. For example, in some variations, the distal tip comprises a retention element that is the most distal portion of the delivery device. In some variations, a retention element is proximal and adjacent to the distal tip.

[0044] FIGS. 4A, 4B, 4C, and 4D – FIGS. 17A, 17B, 17C, and 17D depict top, side, front, and perspective views, respectively, of variations of distal portions of delivery devices comprising distal tips. Some of these distal tips comprise distal edges and/or lateral protrusions as described above. Each variation will be described with respect to the distal edge, lateral protrusions, relationship between retention element and distal tip and/or other defining characteristics. FIGS. 4A-8D show views of distal tips that comprise bulbous distal edges (402, 502, 602, 702, and 802 respectively) and bulbous lateral protrusions (404, 504, 604, 704, and 804 respectively). The variations shown in FIGS. 4A-4D and 8A-8D have distal tips that comprise uniform bulbous structures, as the side views shown in FIGS. 4B and 8B appear as ovals without angles or flat surfaces. The variation in FIGS. 4A-4D comprises a retention element (406) that is positioned adjacent and proximal to the distal tip, whereas the distal portion of the delivery device shown in

FIGS. 8A-8D does not comprise a retention element. The variation in FIGS. 5A-5D comprises a bulbous distal tip structure with flat edges (508) on a side facing away from the elongate shaft. The variation in FIGS. 6A-6D comprises a distal edge that is bulbous when viewed in profile, but flat when viewed from above. The variation shown in FIGS. 7A-7D comprises a distal tip with a bulbous base (706) and two, smaller bulbous lateral protrusions (704).

[0045] The variation of distal tip shown in FIGS. 9A-9D comprises a blunted distal edge (902) and bulbous lateral projections (904). FIGS. 10A-13D depict variations of distal tips that comprise blunted distal edges (1002, 1102, 1202, and 1302, respectively) and blunted lateral protrusions (1004, 1104, 1204, and 1304, respectively). The variation shown in FIGS. 10A-10D comprises lateral grooves (1006) on the side of the distal tip that faces the ET tube when the delivery device is advanced along the ET tube. The variation shown in FIGS. 11A-11D comprises a distal tip that tapers from the distal edge to the proximal edge (1108) to form a mushroom shape when viewed from above in FIG 11A. FIGS. 12A-13D show variations of distal tips that are distinguished by the side facing away from an ET tube when the delivery device is advanced along an ET tube. This side comprises a sloped distal portion (1208 and 1308, respectively). In the variation shown in FIGS. 12A-12D, this sloped distal portion has a length greater than half of the length of the distal tip and the variation in FIGS. 13A-13D comprises a sloped distal portion that is less than half of the length of the distal tip.

[0046] FIGS. 14A-14D depict a variation of distal tip that comprises a blunted end (1402) without lateral protrusions. The distal tip in FIGS. 15A-15D comprises a bulbous end (1502) without lateral protrusions. In the variations of distal tip in FIGS. 16A-17D, the distal tip comprises a retention element (1606 and 1706, respectively). The variation in FIGS. 16A-16D also comprises blunted lateral protrusions (1606), whereas the variation in FIGS. 17A-17D does not comprise any lateral protrusions.

[0047] One or more portions of the distal tip may comprise one or more materials that may be compliant (e.g., elastomer, foam), which may decrease the risk of trauma to the vocal cords if these portion or portions of the distal tip engage the vocal cords or other tissue. In some variations, it may be advantageous for the distal tip to comprise more than one material that may have different material properties. For example, a stiff material may increase the likelihood that the distal tip may be easily advanced past the epiglottis and a more compliant material may

decrease the risk of trauma to tissues that the distal tip may engage (e.g., the vocal cords). FIGS. 18A, 18B, 18C, and 18D – FIGS. 24A, 24B, 24C, and 24D depict top, side, front, and perspective views, respectively, of variations of distal tips that comprise more than one material. In these examples, the one or more materials of a first, outer section (1802, 1902, 2002, 2102, 2202, 2302, and 2402, respectively) may be more compliant than the one or more materials of a second, inner core section (1804, 1904, 2004, 2104, 2204, 2304, and 2404, respectively) The structure of these distal tips may be such that the more compliant section may be an outer section most likely to engage tissue and the more rigid section may be an inner core. The inner core may comprise any suitable shape, and this may distinguish one variation of distal tip from another.

[0048] The variation of distal tip in FIGS. 18A-18D comprises a rectangular inner core (1804) on the ET tube side (the side closest to an ET tube when the delivery device is advanced along an ET tube) of the elongate passageway. FIGS. 19A-19D depict a variation that comprises a T-shaped inner core (1904). The variations shown in FIGS. 20A-20D and FIGS. 21A-21D comprise inner cores (2004 and 2104, respectively) that are rectangular and surround the distal outlet of the elongate passageway. The overall shape of the distal tip shown in FIG. 20A, a top view, is rectangular. The overall shape of the distal tip shown in FIG. 21A, a top view, is slightly tapered on one side (2106). The variation shown in FIGS. 22A-22D comprises an inner core that's cup shaped. FIGS. 23A-23D and 24A-24D depict variations that comprise slits (2306 and 2406, respectively) in the outer section. The variation shown in FIGS. 23A-23D comprises 2 slits and the variation shown in FIGS. 24A-24D comprises 4 slits.

[0049] Of note, the area between the two vocal cords (the rima glottidis), has a smaller cross sectional area than the cross sectional area of the airway just proximal to the vocal cords. In some variations, the shape and/or materials of the distal tip may reduce the likelihood that the distal tip may be advanced distal to the vocal cords, which may reduce the risk of trauma to the vocal cords. For example, the distal tip may have a cross sectional area larger than the area between the vocal cords (the rima glottidis). This may result in a user feeling resistance to advancement if the distal tip engages the vocal cords and may reduce the risk of further advancement past the vocal cords.

[0050] In some variations, the structure and/or materials of the distal tip may reduce the risk of trauma to tissue if the distal tip is advanced past the vocal cords. For example, the distal tips in

FIGS. 25A and 25B show perspective views of variations of the distal tip of delivery devices (2500 an 2501) that may be advanced distal to the vocal cords. The distal tips in these variations each comprise a skirt member (2502 and 2503) that may have a thickness that tapers toward a distal end of the skirt member, which may allow the skirt member (2501 and 2503) to have a narrower profile at its distal end to facilitate introduction between an ET tube and the vocal cords. In some variations, the skirt member (2502 and 2503) may be curved to further facilitate introduction of the skirt member past the vocal cords. While shown in FIG. 25A as being attached to the elongate shaft (2505), in variations of the delivery device that comprise a lid piece (2508) and a grooved piece (2506), the skirt member (2502 and 2503) may be attached to the lid piece or the grooved piece.

[0051] The distal tip of the delivery device may be integrally formed with the elongate shaft (e.g. by overmolding) or may be formed separately and connected in any suitable manner (e.g., via adhesive, ultrasonic bonding, welding, or the like).

Handles

[0052] The delivery device may comprise one or more handles that may have one or more functions (e.g., manipulate the delivery device, secure the catheter, remove a lid). For example, one or more handles may be held by user in order to maneuver the delivery device. The longitudinal length of a handle for manipulating a delivery device may be at least one inch and may comprise ridges, projections, or indentations to facilitate gripping. As shown in FIGS. 2A and 2B, the delivery device (200) comprises one handle (204) that may be held by a user in order to control the delivery device. FIGS. 26A and 26B show magnified perspective views of this handle (204). A handle may comprise a lock in order to secure a suction catheter (not pictured) in the lumen of the delivery device, which may help keep the suction catheter stationary relative to the delivery device while the delivery device is moved (e.g., while the delivery device is advanced in an airway). For example, the lock in FIGS. 26A and 26B comprises a tapered inlet (2602) that is continuous with the delivery device lumen and the proximal insertion inlet (210) where a suction catheter is inserted into the delivery device. The tapered inlet (2602) may taper from the cross-sectional area of the proximal insertion inlet (210) to a cross-sectional area smaller than the proximal insertion inlet and smaller than the cross-sectional area of one or more catheter sizes. After a suction catheter has been inserted through the proximal insertion inlet into

the lumen of the delivery device, the portion of the catheter at the proximal insertion inlet may be moved into the tapered inlet (2602). The catheter may be secured in the tapered inlet (2602) by being compressed or otherwise held by friction, as the tapered inlet cross-sectional area may be less than the cross-sectional area of the catheter. A lock may secure the suction catheter in any suitable manner (e.g., via clip, adhesive, suction). Any suitable portion of the delivery device may comprise a lock (e.g., one or more handles, the distal tip, the elongate shaft) or the lock may be attached to the delivery device and/or the suction catheter at any suitable position.

[0053] During advancement of a delivery device into an airway, a handle may serve as a stop to indicate that the delivery device has been inserted a desired distance, as will be discussed in more detail herein. The handle's transverse cross-sectional area may be larger than the transverse cross-sectional area of the elongate shaft and large enough to increase the likelihood that the handle will engage a patient's tissue (e.g., the teeth). Other structural and/or material features of the handle may increase the likelihood that the handle engages a patient's tissue (e.g., ridges, protrusions). During advancement, a handle on a proximal end of the delivery device may engage a patient's teeth which may reduce the risk of further advancement. Halting advancement of the delivery device after a desired length of the delivery device has been inserted into the airway may reduce the risk of advancing the distal tip of the delivery device distal to a desired location in the airway (e.g., in proximity to the vocal cords).

[0054] In some variations, the delivery device may comprise more than one handle that may have one or more of the same or different functions. For example, in FIGS. 3A and 3B, the delivery device comprises a first handle (303) and a second handle (305). The first handle (303) is connected to the grooved piece (302) and the second handle (305) is connected to the lid piece (304), each of which may be manipulated to manipulate the grooved piece (202) and the lid piece (204), respectively. This may allow a user to control the grooved piece and the lid piece independently. For example, in variations where the lid piece is slidably attached to the grooved piece, a user may hold the first handle stationary while withdrawing the second handle proximal to the first handle. This may slide the lid piece proximally relative to the grooved piece, which may open a side of the grooved piece in order to release a catheter that was contained in the delivery device lumen. The one or more handles may be positioned on any suitable portion or portions of the delivery device. The one or more handles may be integrally formed with other components of the delivery device (e.g., grooved piece, lid) or may be formed separately and

connected in any suitable manner. One or more portions of the handle may comprise a compliant material (e.g., elastomer, foam) that may reduce the risk of damage to a patient's tissue (e.g., the teeth). For example, as described, in some variations of the delivery device, the handle may engage a patient's teeth to indicate that the delivery device has been advanced a desired distance into an airway. The portion of the handle that may engage a patient's teeth may be constructed or coated with one or more compliant materials.

Retention Elements

[0055] The delivery device may comprise one or more retention elements or engagement cuffs that may connect or otherwise align with an ET tube, which may allow the one or more retention elements to guide the delivery device along the ET tube. In some variations, such as shown in FIG. 25B, one or more retention elements may be wings (2518) or other structures that track with an ET tube, but may not connect to the ET tube. In other variations, one or more retention elements may be configured to at least partially encircle an ET tube to temporarily connect the retention element to the ET tube. In some variations, such as shown in FIGS. 2A and 2B, one or more retention elements (208, 209) may be configured to partially encircle the ET tube. In these variations, the one or more retention elements (208, 209) may engage an ET tube or be removed from an ET tube anywhere along the length of the ET tube. In other variations, one or more retention elements may be configured to completely encircle the ET tube. In some of these variations, the one or more retention elements may be slid proximal to the proximal end of the ET tube to decouple the delivery device from the ET tube. In other variations, one or more retention elements may be configured to be frangible such that the one or more retention elements may be broken or otherwise converted into partially-tubular members, which may allow the removal of the one or more retention elements anywhere along the length of the ET tube. The one or more retention elements may be rigid or flexible and may be sized to connect with one or more ET tube sizes. For example, a delivery device may comprise one or more retention elements that are flexible in order to accommodate ET tubes with outside diameters between 9-12mm.

[0056] While shown in FIGS. 2A and 2B as having two retention elements (208, 209), it should be appreciated that the delivery device (200) may include any number of retention elements (e.g., one, two, three, or four or more retention elements). Additionally, while each of

the retention elements (208, 209) are shown in FIGS. 2A and 2B as being connected to the elongate shaft (202), it should be appreciated that some or all of the retention elements may be connected to any suitable portion of the delivery device. For example, in some variations of the delivery device comprising a lid piece, one or more of the retention elements may be connected to the lid piece. In some variations one or more retention elements may be connected to the distal tip. It should be appreciated that in variations of the delivery device comprising more than one retention element, the more than one retention elements may be attached to different portions of the delivery device (e.g., one attached to the elongate shaft and one attached to the distal tip).

[0057] When the delivery device is curved, as is described in more detail herein, the one or more retention elements may extend away or toward a center of curvature of the delivery device. In variations where the one or more retention elements (208, 209) extend away from a center of curvature of the delivery device (200), such as shown in FIGS. 2A and 2B, the delivery device (200) may be connected to an inner curvature of an ET tube. When advanced along an inner curvature of an ET tube, a distal tip (206) of the delivery device (200) may be advanced to an anterior side of the vocal cords. Conversely, when the one or more retention elements extend toward a center of curvature of the delivery device, the delivery device may be connected to an outer curvature of an ET tube. When advanced along an outer curvature of an ET tube, the distal tip of the delivery device may be advanced to a posterior side of the vocal cords.

[0058] In some variations, the one or more retention elements may be sized and configured to reduce the risk of advancement of the retention elements past the vocal cords or other tissue structures of the airway. In these variations, the one or more retention elements may limit the forward advancement of the delivery device into the airway. In some of these variations, the delivery device may be configured such that the distal tip of the delivery device is positioned proximally of the vocal cord when the one or more retention elements engage the vocal cords or other tissues of the airway. In other variations, the distal tip of the delivery device may be advanced distally of the vocal cords when the one or more retention elements engage the vocal cords or other tissues of the airway. The one or more retention elements may be configured to minimize the distance between the delivery device and the ET tube while the delivery device is advanced along the ET tube. It may be advantageous for the delivery device to track closely to the ET tube in order to minimize the risk of the delivery device contacting and/or traumatizing

airway tissue. For example, in some variations of the delivery device, it may be advantageous for a retention element to be positioned close to the distal tip in order to reduce the risk of the distal tip deflecting away from the ET tube. In some of these variations, the distance between the distal tip of the delivery device and a most distal retention element may be less than 2 cm.

Other Delivery Device Design Characteristics

[0059] In some variations, the delivery device may be configured to be curved during advancement of the delivery device, which may allow the delivery device to follow the anatomy of the trachea. When the delivery device is coupled to or aligned with an ET tube, the curvature of the delivery device may match a curvature of the ET tube. The delivery device may be pre-formed straight and be flexible in order to conform to the shape of an airway or ET tube. Alternatively, the delivery device may be pre-formed with a curve and be flexible or rigid. For example, in some variations, the delivery device may have a pre-formed curve with a radius of curvature between 3.9 inches and 12 inches. In some of these variations, the radius of curvature may be approximately 8 inches. The delivery device may be flexible and may be capable of bending to a bend radius of approximately 2 inches. The initial radius of curvature and allowable bend radius may facilitate the use of the delivery device in a range of airways (e.g., straight, curved, narrow) and/or may indicate to a user where on an ET tube the delivery device should be aligned (e.g., on the underside). The deflection force needed to achieve a 2 inch bend radius may be sufficiently low to allow the delivery device to conform to the shape of an ET tube without changing the shape of the ET tube curve. In some variations, the delivery device may require a deflection force less than 1 lbf to bend from an initial 8 inch radius of curvature to a 2 inch radius of curvature. In some of these variations, the deflection force required may be less than 0.25 lbf.

[0060] One or more portions of the delivery device may have a permanent curvature (e.g., may be pre-formed with a curve) and/or be flexible. For example, in some variations, the elongate shaft may be pre-formed with a curve. In some variations of the delivery device that comprise a lid piece, the lid piece may be pre-formed with a curve. In others of these variations, the lid piece may be flexible, and the lid piece may conform to the curvature of the grooved piece when the lid piece is releasably connected to the grooved piece. In other variations, the lid piece may be pre-formed with a curve and the grooved piece may be flexible. In these variations, the

grooved piece may conform to curvature of the lid piece when the lid piece and grooved piece are releasably connected. In still other variations, both the lid piece and the grooved piece may be flexible, such that the delivery device may take on a specific curvature or otherwise conform to the patient's anatomy or an ET tube. It should also be appreciated that in some variations a straightened or curved stylet may be inserted into a portion of the delivery device (e.g., the lumen in the elongate shaft) to alter the curvature of the delivery device.

[0061] It may be advantageous for some variations of the delivery device to comprise an indicator of a maximum insertion distance. The maximum insertion distance may be defined as the distance a delivery device may be inserted into a patient's airway that should not be exceeded. Advancing a delivery device farther than this maximum insertion distance may increase the risk of trauma to a patient's tissue (e.g., a patient's vocal cords). The distance may be defined in relation to a portion of the patient, such as the patient's teeth. If resistance to advancement of the delivery device is felt by a user, the user may stop advancing the delivery device as the resistance may be an indicator that a portion of the delivery device may be engaging a patient's tissue. However, in some cases, the distal end of the delivery device may be advanced to a desired location (e.g., in proximity to a patient's vocal cords) before resistance is felt by a user. In these situations, a proximal alignment region on the delivery device may indicate that the maximum insertion distance has been reached and may reduce the risk of further advancement, which may reduce the risk of engaging and/or traumatizing a patient's tissue. For example, in some variations, a maximum insertion distance may be determined to be 10cm from a patient's teeth. When a delivery device is inserted this maximum insertion distance, as measured from the most distal portion of the delivery device to the patient's teeth, the most distal portion of the delivery device will have reached or passed the vocal cords in less than 5% of individuals.

[0062] The maximum insertion distance may be indicated to a user in any suitable way. For example, the delivery device may comprise a proximal alignment region, which may be a marking (e.g., on the elongate shaft, on the handle) that is located the maximum insertion distance from the most distal portion of the delivery device (e.g., the distal end of the distal tip). The marking may be aligned with a portion of a patient (e.g., a patient's teeth) if resistance to advancement has not been felt by a user prior to this alignment. The delivery device may comprise one or markings that may be used for patients with one or more different

characteristics (e.g., gender, height, age) that may be correlated with different sized airways. In other variations, the delivery device may comprise one or more features that engage a portion of a patient (e.g., a patient's teeth) to indicate that the delivery device has been inserted the maximum insertion distance. For example, a handle may contact a patient's teeth during advancement and may indicate that the delivery device has been inserted the maximum insertion distance.

[0063] In the variation shown in FIGS. 27A and 27B, the delivery device (2700) comprises an alignment clip (2702) that attaches to a portion of the delivery device. The alignment clip may be an indicator of the maximum insertion distance. For example, the alignment clip (2702) may be positioned such that a distal edge (2704) of the alignment clip engages the teeth of a patient when the delivery device has been inserted a maximum insertion distance. The alignment clip may be positioned to indicate a maximum insertion distance for patients with one or more characteristics (e.g., female patients who have shorter airway lengths on average than male patients) and it may be removed or repositioned for use with patients with one or more other characteristics (e.g., male patients who have longer airway lengths on average than female patients). For example, as shown in FIGS. 27A and 27B, the distance from the distal end of the distal tip (2706) to the distal edge (2704) of the alignment clip may be approximately 10cm, which may be the maximum insertion distance for female patients. The alignment clip may be removed in order to use the delivery device with male patients. The distance from the distal end of the distal tip (2706) to a portion of the handle (2708) that may contact a male patient's teeth may be 11cm, which may be the maximum insertion distance for male patients.

[0064] As mentioned, the systems described here may comprise a delivery device and a suction catheter. In some variations, the suction catheter may be preloaded into a lumen of the delivery device. In some variations where a stylet is positioned in the suction catheter, the stylet may also be preloaded into the suction catheter. In some variations, the delivery device may not be preloaded with a suction catheter. The suction catheter may be any suitable suction catheter, and may include any configuration of elements. In some variations, the suction catheter may comprise a single suction outlet or may comprise a plurality of suction outlets. In some variations, the suction catheter may comprise an atraumatic distal tip to reduce the risk of trauma to airway tissue (e.g. vocal cords). In some variations, the atraumatic distal tip may comprise one or more compliant materials (e.g., foam) and/or structures (e.g., rounded edges) that reduce the

risk of tissue trauma. In some variations, the atraumatic distal tip may comprise a distal sponge member, and in these variations suction may be applied through the sponge member. In some variations, at least a distal portion of the suction catheter may be flexible, which may allow the suction catheter to bend when contacting tissue and minimize the risk of the suction catheter tip puncturing or otherwise damaging tissue.

[0065] In another variation, the suction catheter 2800 comprises a separate suction connector (2802), as shown in FIG. 28B, which may be attached to the catheter shaft (2804) of the catheter (2800). This may facilitate, for example, the removal of the suction guide after the catheter shaft (2804) of the catheter (2800) is positioned in the body of the patient. This may permit the withdrawal of the guide without blocking or interference from the suction connector (2802). Then, after withdrawal of the guide, the suction connector may then be attached to the catheter shaft (2804), as depicted in FIG. 28A, and coupled to a suction source for removal of secretions.

[0066] Referring to FIG. 28B, the catheter shaft (2804) comprises a proximal end (2806) and a distal end (2808), with a connector interface (2810) located at the proximal end (2806) configured to attach to a corresponding shaft interface (2812) located at the distal end (2814) of the suction connector (2802). The proximal end (2816) of the suction connector (2802) may be configured with a medical connector for attachment to a suction source, e.g. wall suction, portable suction unit and a suction syringe, for example. The connector may be a Luer connector, barb, multi-step barb or any other standardized connector which provides a sealed interface to permit fluid transfer through the connector.

[0067] The interface between the connector interface (2810) and shaft interface (2812) may be configured in a variety of ways to provide a sealed connection therebetween. In some variations, the interface may be configured to provide reversible attachment, such that the suction connector (2802) may be attached and re-attached to catheter shaft (2804), while in other embodiments, the hub may be configured to attach to the catheter shaft (2804) once, while resisting detachment. In some variations, the interfaces may comprise a threaded interface, a friction fit interface, a barbed interface, a snapfit, a Luer lock interface, a bayonet mount interface, a quick connect interface (e.g. John Guest fitting), and the like. In some variations, the suction connector and/or the shaft interface may comprise a releasable latch to facilitate detachment of the suction connector, while in other embodiments, the suction connector and catheter interface may

comprise a ramped surface with a flange or recess which permits sliding up and over the ramped surface while resisting movement in the opposite direction.

[0068] The catheter shaft (2804) may be a single lumen or multi-lumen body and may comprise one or more distal openings (2818) and/or side openings (2820) for each lumen. Likewise, the suction connector (2802) may be configured with a corresponding number of lumens and proximal openings corresponding to the lumen(s) of the tubular body (2804). The suction connector (2802) may optionally comprise a flow control (2822), such as stopcock or valve to open and close the lumen, and/or switch connections between a lumen and a proximal opening of the suction connector, for example. In some further variations, the flow control (2822) may comprise a control lumen which is in communication with the internal lumen of the suction connector (2802) and to the atmosphere, which may be selectively closed or occluded using a cap (2824) which may or may not be attached to the connector (2802) or catheter shaft (2804) by a tether (2826). In use, the cap (2824) may be placed over the control lumen to maintain occlusion of the control lumen so that any suction or vacuum source coupled to the proximal end (2816) of the suction connector (2802) is in isolated fluid communication with distal end (2808) of the catheter shaft (2804) to facilitate removal of secretions. When the cap (2824) is removed so that the control lumen is open to the atmosphere, the suction or vacuum source is no longer in isolated fluid communication with the distal end (2808) of the catheter shaft (2804) and primarily draws air from the atmosphere through the flow control (2822). However, by occluding the control lumen of the flow control (2822) with his or her finger, the user may easily and selectively reestablish or break isolated fluid communication with the distal end (2808) of the catheter shaft (2804) to apply suction or to stop suction, so that any body tissue or or material that may be occluding the distal end (2808) of the shaft may be separated, which may facilitate removal of secretions. The flow control (2822) may optionally comprise a seat or flange (2830) surrounding the control lumen, to facilitate positioning of the user's finger to occlude the flow control (2822).

[0069] The catheter shaft may comprise any of a variety of catheter materials, including silicone, nylon, polyethylene, polypropylene, polytetrafluoroethylene, polyvinyl chloride and the like. The catheter shaft may comprise one or more materials to make it radiopaque and therefore visible on a radiographic image. The connector interface, and suction connector may be constructed from one or more materials, such as metal, ceramic, or plastic. Some suitable

plastics that may be used include polypropylene, polyethylene, polyvinyl chloride, nylon, acrylonitrile butadiene styrene or the like. The lumen of the suction connector may comprise a circular cross-sectional shape, or any other suitable shape that allows fluid and debris from the suction catheter to travel through it. The catheter shaft may have a length in the range of about 4 cm to about 40 cm or more, and may have an external diameter size from about 3F to about 14F or more. The lumen of the suction connector may be sized to provide a complementary interfit with the external diameter of the catheter shaft.

[0070] In some variations, the suction catheter shaft may be reinforced along a portion of the shaft length, comprising an atraumatic distal end and distal region, a proximal region, and a central shaft region. In some variations the proximal and/or central shaft region may be reinforced, compared to the atraumatic tip or distal region, which may prevent or reduce the risk of suction catheter displacement after initial placement in the patient's airway. It is hypothesized that certain patients may dislodge the suction catheter with their tongue if the proximal and/or central regions of the catheter shaft are too flexible. The reinforcement or stiffness may be characterized by a three-point bend test, wherein the maximum deflection force in a three-point bend is <0.1 lbf for the atraumatic tip and 0.20 lbf to 1.0 lbf for the central shaft region. In other variations, the maximum deflection force is in the range of about 0.30 lbf to about 0.40 lbf, or about 0.40 lbf to about 0.45 lbf for the central region.

[0071] In some embodiments, the catheter shaft may comprise one or more metal or semi-rigid plastic reinforcement structures or members which are partially located along the proximal and/or central region of the catheter shaft. The tongue reinforcement structure may be attached to the outer surface or lumenal surface of the catheter shaft, or may be embedded within the wall of the catheter shaft. In one particular embodiment, the catheter shaft may comprise an elongate reinforcement member located within the lumen of the catheter shaft, wherein the proximal end of the reinforcement member is welded or otherwise attached to the catheter shaft or suction connector, while the distal end of the reinforcement structure may be attached or may be free-floating or otherwise unattached within the lumen. In other variations, the reinforcement structure may comprise a helical or woven structure, and may be welded, adhered, and/or embedded partially or fully along the length of the catheter shaft. In some further variations, the reinforcement structure may have a variable stiffness along its length, e.g. the cross-section shape of the reinforcement structure may decrease from a proximal location to a distal location.

In other variations, the reinforcement structure may comprise a coating or thin-walled film, and may be bonded, adhered, and/or embedded partially or fully along the length of the catheter shaft. In some variations, the catheter shaft has a length of about 25 cm to about 40 cm, an external diameter in the range of about 10 Fr to about 14Fr. The elongate reinforcement structure has a length of about 25 cm to about 40 cm, or about 30 to about 35 cm. In some variations, the elongate reinforcement structure has a shorter length than the catheter shaft. In some further variations, the distal end of the elongate reinforcement structure is located about 2 to about 10 cm proximal, to the distal tip of the catheter shaft, and in other embodiments, may be located about 2 cm to about 5 cm proximal to the distal tip of the catheter shaft.

[0072] FIGS. 28C and 28D schematically depict the suction catheter (2800) of FIGS. 28A and 29B with an optional reinforcement member (2828). In this particular embodiment, the connector interface (2810) comprises a threaded annular body formed with a rigid material, such as a rigid polymer, ceramic or metal. Bonded, adhered, or welded to, or integrally formed with the annular body is a proximal end (2830) of a reinforcement member (2828) that comprises a hard plastic or metal wire or filament. The proximal end (2830) may be located against an inner lumen surface of the annular body while the body (2832) and the distal end (2834) of the reinforcement member may be located within the longitudinal lumen of the catheter shaft (2804). The body (2832) and/or the distal end (2834) may also be bonded, adhered, or welded to the catheter shaft, or may be unattached or free floating within the longitudinal lumen of the catheter shaft (2804). In other variations, the reinforcement member may be located within the wall of the catheter shaft (2804) or may be located in a second lumen of the catheter shaft (2804) separate from the primary lumen used for suction. In this embodiment where the reinforcement member comprises a metal wire, the wire may have a length of about 30 cm to about 35 cm, and/or may be configured so that the distal end (2834) of the reinforcement member (2830) is located about 2 cm to about 5 cm proximal to the distal tip (2818) of the catheter shaft (2804).

[0073] FIGS. 30A and 30B depict another embodiment of the suction catheter connector (3000), comprising a first end (3002), a second end (3004), and a connector lumen (3006) therebetween. The first lumen region (3008) in the first end (3002) may comprise a constant or variable diameter or cross-sectional size. The taper may be in the range of about 0.25 degrees to about 3.0 degrees. For example, the first lumen region (3008) may be larger at the first opening (3010) and slightly taper toward a more central location. In some variations, the taper may

facilitate insertion of a catheter shaft into the first lumen region (3008). The first end (3002) may comprise one or more external flanges (3012), which may facilitate insertion of the first end (3002) into the opening or lumen of a suction source.

[0074] The second end (3004) of the connector (3000) may comprise a constant or variable diameter or cross-sectional size. In the particular example depicted in FIG. 30B, the second lumen region (3014) at the second opening (3016) has a taper in the range of about 30 degrees to about 60 degrees and has a length of about 0.015 inches to about 0.025inches. A third lumen region (3018) may be provided that is contiguous with the second lumen region (3014), but has a different taper angle in the range of about 2.0 degrees to about 3.0 degrees. The length of the third lumen region (3018) may be in the range of about 0.20 inches to about 0.40 inches. The third lumen region (3018) may have smooth transition to the fourth or central lumen region (3020), or may comprise a step-off (3022) as depicted in FIGS. 30B and 30C.

[0075] As depicted in FIGS. 30B and 30C, the third lumen region (3018) and/or fourth or central lumen region (3020) may also comprise one or more projections (3024). In some variations the projection (3024) may form an interfit or resistance fit with a corresponding opening on the catheter shaft, when inserted into the suction connector (3000). The projection (3024) may be configured to facilitate insertion of the catheter shaft into the connector 3000, while providing some resistance to removal of the catheter shaft. In the particular embodiment depicted in FIG. 30C, the projection (3024) may comprise a leading surface (3026) that is closer to the second opening (3016) and may be configured with an open angle (3034) from the plane through the base of the projection (3024) of about 135 degrees to about 165 degrees. The trailing surface (3028) of the projection (3024) may be configured with an open angle (3036) in the range of about 50 degrees to about 90 degrees. As depicted in FIG. 30C, in some variations, the trailing surface (3028) has a smaller angle than the leading surface (3026). The projection (3024) may also comprise an upper surface (3030) between the leading (3026) and trailing surfaces (3028). The upper surface (3030) may be parallel or angled to the longitudinal axis of the connector lumen, and may be located at a maximum orthogonal height in the range of about 0.020 inches to about 0.035 inches from the base (3032) of the projection (3024). The projection (3024) may be located about 0.25 inches to about 0.35 inches from the second opening (3016) of the suction connector (3000).

[0076] FIGS. 31A and 31B depict the suction connector (3000) of FIGS. 30A to 30C, and a catheter shaft (3100) inserted into and sealably coupled to the second end (3004) and second of the connector (3000). As depicted in FIG. 31B, the catheter shaft (3100) has been inserted through the second opening (3016) and through the third and fourth lumen regions (3018, 3020) such that the projection (3024) reside in a projection opening (3102) of the catheter shaft (3100). The projection opening (3102) may be located at about 0.1 inches to about 0.25 inches from the proximal opening (3104) of the shaft (3000). There may be one, two or three, four or more projection openings on the catheter shaft (3000). The openings (3104) may comprise a circular, oval, oblong, square, rectangular, or any other of a variety of shapes and sizes configured to receive the projection (3024) of the suction connector (3000). In the specific example depicted in FIG. 31B, the openings (3104) have circular shapes and have a diameter or maximum transverse dimension of about 0.080 inches to about 0.120 inches. As shown in FIG. 31B, the leading surface (3026) of the projection (3024) has an angle or slop that facilicates sliding or displacement of the catheter in the inward direction. After insertion, the trailing surface (3028) abuts the inner surface (3106) of the opening (3104) to form a generally transverse interface to the longitudinal axis of the catheter shaft (3100) and the suction lumen (3006) of the suction connector (3000), which resists withdrawal of the catheter shaft (3100) outward direction. To uncouple the projection (3024) from the projection opening (3104), the shaft (3100) and connector (3000) may be rotated relative to each other, and then separated from each other. In some embodiments, there may be an optional second projection (3108) in the fourth or central lumen region (3006). This second projection (3108) may act as a physical barrier to prevent advancement of the suction catheter (3100) past this second projection (3108) when the suction catheter (3100) is inserted into the second end (3004) of the suction connector (3000).

[0077] The suction connector (3000) may also further comprise a flow control (3034) comprising a control opening (3036) with a control lumen (3038) in fluid communication with the connector lumen (3006). As noted previously, the control lumen of the flow control (3034) may be selectively occluded with the user's finger, so that the user may easily and selectively reestablish or break isolated fluid communication with the catheter shaft. This particular embodiment does not include a cap or plug to occlude the control lumen (3038), but may be provided separately and may be coupled by a looped tether to the suction connector (3000).

[0078] In some variations, a kit may comprise the devices and/or systems described here. For example, in the variation shown in FIG. 29, the kit comprises the suction catheter (2900) with a suction connector (2902) and catheter shaft (2904), suction guide (2906), and provided in a sealed packaging (2908). In some instances the sealed packaging may also be sterilized. In some variations, the suction catheter may be pre-attached to the suction connector in the kit, but in other variations, may be provided in a separated state in the kit. The kit may also optionally include other components, such as a one-way valve that may be coupled to the proximal end of the suction connector, or between the suction connector and the tubular body. The kit may also optionally further comprise items for securing the suction catheter after insertion into the patient, such as a clip, clamp, or adhesive tape. In other variations, a kit may comprise oral hygiene items for an intubated patient, which may comprise a variation of the delivery device and/or suction catheter described here. The oral hygiene items may include, for example, as a toothbrush, toothpaste, mouth rinse, gels and/or mouth swabs and other items used for mouth care in mechanically ventilated patients. It should be appreciated that this kit may comprise any number of suitable pouches (e.g., one, two, three, four, five) or packaging elements (e.g., boxes, trays).

Methods

[0079] Described here are methods of a delivery of a suction catheter to the airway of a patient. For example, the delivery devices described above with respect to FIGS. 2A, 2B, and 3A-3E may be used to deliver a suction catheter to an airway of a patient intubated with an ET tube. Generally, the delivery device may be slidably connected to an ET tube, and the delivery device may be advanced along the ET tube to position a distal outlet of the lumen of the delivery device at or near the vocal cords. In variations where the delivery device comprises one or more retention elements, the one or more retention element may be placed at least partially around the ET tube to slidably connect the delivery device to the ET tube. In some variations of the delivery device comprising more than one retention element, all retention elements may be attached to the ET tube at the same time, prior to advancement of the delivery device. In other variations, however, all retention elements may not be attached to the ET tube at the same time, which may be due to the position of the retention elements on the delivery device. For example, a retention element may be positioned on the proximal end of a delivery device and a retention element may be positioned on the distal end of the delivery device. Initially, only the distal retention element

may be attached to the ET tube as the proximal retention element may be proximal to the proximal end of the ET tube. As the delivery device is advanced into the airway and along the ET tube, the proximal retention element moves distally past the proximal end of the ET tube and may then be attached to the ET tube. In some variations, the delivery device may be advanced along an inner curve of the ET tube. In other variations, the delivery device may be advanced along an outer curve of the ET tube.

[0080] When the delivery device is advanced along the ET tube, the delivery device may be advanced to position a distal outlet of a lumen of the delivery device at or near the vocal cords. In some variations, the delivery device may be advanced until the delivery device (e.g., the distal tip or retention element of the delivery device) engages airway tissue in proximity to the vocal cords, such as the ventricular folds, corniculate cartilage, or cuneiform cartilage. A user may feel resistance to further advancement when the delivery device engages airway tissue and may stop advancing the delivery device at that point, which may reduce the risk of tissue trauma. In other variations, it may be advantageous to advance the delivery device such that the likelihood of engaging airway tissue with the distal tip of the delivery device is minimized, which may reduce the risk of tissue trauma. The distance between a patient's vocal cords and other portions of the patient (e.g., the teeth of the patient) may be variable, but advancing a delivery device a predetermined, maximum insertion distance into an airway (e.g., 10-11 cm from the distal tip of the delivery device to a patient's teeth) may reduce the risk of engaging airway tissue in most patients. In some variations, advancement of the delivery device until there is an alignment of a proximal alignment region of the delivery device with a portion of the ET tube or the patient may indicate that the delivery device has been advanced the maximum insertion distance. For example, the delivery device may comprise a marking that is the maximum insertion distance from the distal end of the delivery device (e.g., a marking that is 10-11cm from the distal tip of the delivery device). The delivery device may be advanced until the marking of the delivery device aligns with a portion of the patient (e.g., the teeth of the patient) or the ET tube (e.g., a proximal end of the ET tube, a marker on the ET tube, or the like).

[0081] In some variations of the delivery device, the portion of the delivery device that may be indicate that the delivery device has been advanced a maximum insertion distance into an airway may be a handle. For example, the delivery device may be advanced along an ET tube into an airway until the handle engages a portion of the patient (e.g., the teeth of the patient) or a portion

of the ET tube (e.g., the proximal end of the ET tube). This may indicate that the delivery device has been advanced into the airway the maximum insertion distance. In variations of the delivery device that comprise a clip, as shown in FIGS. 27A and 27B, the clip (2702) may be positioned such that the distal edge (2704) of the clip is a maximum insertion distance from the distal tip (2706) of the delivery device. The delivery device may be advanced until the clip is aligned with or engages a portion of the patient (e.g., the teeth of the patient) or a portion of the ET tube (e.g., the proximal end of the ET tube). The clip may be movable between positions on the elongate shaft for patients with one or more different characteristics. For example, the clip may be positioned in one location on the delivery device for female patients (who have shorter airway lengths on average) and positioned in another location for male patients (who have longer airway lengths on average). In some variations, for female patients the clip may be in one position and used for alignment and for male patients the clip may be removed and a handle that is proximal to the clip position may be used for alignment. If resistance to advancement is felt by a user prior to advancing the measuring device the maximum insertion distance, the user may stop advancing the delivery device.

[0082] In some variations, one or more portions of the delivery device may be advanced distally of the vocal cords and into the trachea. For example, in variations where the delivery device comprises a skirt member, at least a portion of the skirt member may be advanced distal to the vocal cords. Additionally or alternatively, when a portion of the delivery device is advanced distally of the vocal cords and into the trachea, the distal outlet may be positioned past the vocal cords. In other variations, the distal outlet may be positioned proximally of the vocal cords. In some of these variations, the distal outlet may be positioned within 2 cm of the vocal cords. In some of these variations, the distal outlet may be positioned within 1 cm of the vocal cords.

[0083] The suction catheter may be loaded into the lumen of the delivery device before or after advancement of the delivery device into the airway. In some instances, the suction catheter may be pre-loaded into the delivery device, such that the suction catheter is advanced with the delivery device. The suction catheter may be pre-loaded into the delivery device in any suitable manner. In variations of the delivery device comprising a lid piece, the suction catheter may be pre-loaded before or after the lid piece has been attached to the grooved piece. In variations where the suction catheter is pre-loaded before the lid piece has been attached, the suction

catheter may be positioned in a channel of the grooved piece, and the lid piece may be connected to the grooved piece to enclose the suction catheter in the lumen of the delivery device. In variations where the suction catheter is pre-loaded after the lid piece has been attached to the grooved piece to form a lumen, the suction catheter may be advanced into a proximal inlet of the lumen. In variations of the delivery device that do not comprise a lid piece, the suction catheter may similarly be preloaded by advancing the suction catheter into a proximal inlet of the delivery device lumen. In these variations, a stylet may aid in advancement of the suction catheter into the lumen. In some variations, the suction catheter is advanced until the distal end of suction catheter is at or near the distal outlet of the delivery device lumen. In variations of the delivery device that comprise a lock, the suction catheter may be secured in the lock after the catheter has been preloaded. This may increase the likelihood that the suction catheter is advanced into the airway with the delivery device.

[0084] In variations, where the suction catheter is loaded into the lumen of the delivery device after advancement of the delivery device into the airway, the suction catheter may be advanced into the proximal inlet of the delivery device lumen. In some variations, a stylet may aid in advancement of the suction catheter into the lumen.

[0085] With the distal outlet of the lumen of the delivery device positioned at or near the vocal cords, the distal end of a suction catheter may be advanced out of the distal outlet of the lumen to advance the distal end of the suction catheter into the area between the ET balloon and the vocal cords. In some of these variations, the distal end of the suction catheter may be advanced until it engages a balloon of the ET tube, as indicated by a user feeling resistance to further advancement of the suction catheter. In variations where a stylet is positioned within the suction catheter, the stylet may aid in advancement of the suction catheter.

[0086] In variations of the delivery device that do not comprise a lid piece or otherwise disengage from the suction catheter while it is in an airway, the suction port of the suction catheter may be connected to suction source after the suction catheter is positioned between the ET balloon and the vocal cords. When suctioning is complete, the delivery device and the suction catheter may be proximally withdrawn from the airway together. In order the reduce the risk of dislodging the ET tube during withdrawal of the delivery device, the ET tube may be secured or otherwise held in place while the delivery device and suction catheter are withdrawn.

[0087] A suction connector may be attached, removed, or reattached to the proximal end of a suction catheter in any of the method variations described above. For example, in some variations, a suction connector may be attached to a suction catheter prior to inserting the suction catheter into a delivery device. In other variations, a suction connector may be attached to a suction catheter prior to withdrawing a delivery device from a patient's airway. A suction connector may also be removed from a suction catheter prior to withdrawing a delivery device and reattached to the suction catheter after withdrawing the delivery device. In other variations, a suction connector may be attached to a suction catheter after withdrawing a suction guide. In still other variations, a suction connector may remain attached to a suction catheter while a suction guide is being withdrawn from a patient's airway and after the suction catheter has been removed from the delivery device.

[0088] As noted previously in FIG. 29, the system may comprise a suction guide (2906) and a suction catheter (2900) provided in a sealed package. The suction catheter (2900) may be provided with the suction connector (2902) and catheter shaft (2904) pre-coupled in the packaging (2908). The suction catheter may or may not be provided or otherwise pre- inserted into a lumen of the suction guide in the package. In use, the package is opened and the device is removed and visually inspected for damage. In embodiments where the suction catheter is pre-inserted in the package, or after the user has inserted the suction catheter into th the suction guide in preparation for insertion, as depicted in FIG. 32 the user may verify that the suction catheter (2900) is visible from within the lumen (3200) of the suction guide (2906). The user may be instructed to adjust the relative positioning between the suction guide and the suction catheter such that the distal tip of the suction catheter is visible but not protruding from the distal tip of the suction guide. Prior to insertion, the suction catheter may be releasably locked to the suction guide, to resist relative motion between them. In the exemplary embodiment depicted in FIGS. 33A and 33B, the suction catheter (2900) is locked by displacing the catheter shaft (2904) from the primary lumen region (3302) of the suction guide (3300), to a secondary lumen region (3304). The primary and secondary lumen regions (3302, 3304) may be configured with a first width and a second width, respectively, where the second width is smaller than the first width, thereby providing frictional fit between the secondary lumen region and the catheter shaft. The suction guide (3300) is then positioned on the underside of an ET tube (3400) that is already positioned in a patient, as shown in FIG. 34. In some variations, the user will capture or position

the pilot line (3402) of the ET tube (3400) between the prongs (3306) of suction guide (3300) and the ET tube (3400), which may reduce the risk that the suction guide (3300 snags or ortherwise engages the pilot line (3402) and pulls, pushes or draws in the pilot line (3402) into the patient's mouth. The suction guide (3300) with suction catheter (2900) in a locked position is then advanced until the handle (3308) of the suction guide (3300) is up against the patient's teeth (3600), lips or gumline, as depicted in FIG. 36A. If significant resistance is encountered, the user may withdraw the suction guide and then attempt to re-advance the suction guide, or an x-ray may be taken to identify any possible misplacement or tissue dissection involving the suction guide.

[0089] Once the suction guide is positioned at the desired location, the suction catheter may be unlocked from the suction guide and then advanced distally while the suction guide is maintained at its current position. When the cuff (3404) of the ET tube (3400) or other resistance it felt, suction catheter advancement is stopped, as illustrated in FIG. 36A. A vacuum source is then connected to the suction connector, e.g. wall suction or other vacuum device, and suction is applied to remove any accumulated secretions from around the ET cuff. During the application of the suction, the suction catheter may be retracted and advanced, and/or rotated in different directions in order to sweep around the ET tube (3400) and reach secretions that have accumulated at different regions around the ET cuff (3404).

[0090] In some variations, the suction catheter and suction guide may be removed immediately after the suction procedure. In other variations, the suction catheter may be left in place so that continuous, intermittent, periodic or as-needed suction may be applied to the patient without having to reinsert the suction guide and suction catheter. In these embodiments, an example of which is depicted in FIG. 36B, while holding the suction catheter (2900) in place against the ET tube cuff (3404), the suction guide (3300) may be slowly withdrawn from the patient's mouth (3602). During the withdraw of the suction guide (3300), the user may apply a distally directed force on the suction catheter (2900), to maintain or feed the suction catheter (2900) against the ET tube cuff (3404) and to otherwise resist inadvertent withdrawal of the suction catheter (2900) along with the suction guide (3300). As depicted in FIG. 35A, the suction connector (2902) may then be separated from the catheter shaft (2904) by holding the catheter shaft (2904) in place and pulling the suction connector (2902) away. As shown in FIG. 35A, the suction connector (2902) may be removed by pulling the connector linearly, but in

other variations, the suction catheter may be configured with a button release or twist-off mechanism for separating the two components. The suction guide may then be slid off or otherwise removed from the catheter shaft of the suction catheter. The catheter shaft may be secured to the ET tube (or patient) using tape, or with a clamp or other attachment mechanism.

[0091] After removal of the suction connector as depicted in FIG. 36C, the suction guide (3300) may be pulled off the catheter shaft (2904). This may be performed even where the catheter shaft 2904 comprises a threaded interface (2910) and the first end (2912) of the suction connector (2902) lacks a corresponding threaded interface. The suction connector (2902) may be reattached to the catheter shaft after removal of the guide. In some variations, the suction connector (2902) may be attached to the catheter shaft (2904) using either end (2912, 2914) of the suction connector (2902). In some further variations, the configurations of the ends (2912, 2914)of the suction connector (2902) may be different, which may permit different ways to attach the suction connector (2902) to the catheter shaft (2904). For example, a first end (2912) of the suction connector (2900) may comprise a resilient or flexible polymer, which may be used to provide a friction fit when the catheter shaft (2904) is inserted into the connector lumen (2916) of first end (2912) of the suction connector (2900). The second end (2914) may comprise a rigid plastic or metal, which may be configured to provide a mechanical interfit with the threaded interface (2910) of the catheter shaft (2904), as depicted in FIG. 35A. As depicted in FIGS. 35A and 35B, the second end (2914) of the suction connector (2902) may be configured with lumenal helical threads, for example, that form a sealed complementary mechanical interfit with external helical threaded interface (2910) on the catheter shaft (2904). As depicted in FIGS. 35B, the threaded interface (2910) permits reattachment of the suction connector (2902) to the catheter shaft (2904) with a rotational or twist-on motion.

[0092] A suction catheter may be secured at any time after it is positioned in a patient's airway to resist its displacement from where it is positioned, and it may be secured using one or more coupling members, such as a clip, clamp, or adhesive tape. A suction connector may also be attached to a suction catheter before or after the suction catheter is secured. For example, in some variations, a suction catheter may be coupled to an endotracheal tube using one or more coupling members after a delivery device has been withdrawn from a patient's airway. In other variations, a suction catheter may be coupled to an endotracheal tube using one or more coupling

members after the suction catheter is positioned in a patient's airway but prior to the withdrawal of a delivery device from the patient's airway.

CLAIMS

We claim:

1. A system, comprising:

a catheter shaft comprising a proximal end, a distal end, and a longitudinal lumen therebetween; and

a suction connector comprising a first end, a second end and a lumen therebetween, wherein the suction connector is configured to be attachable to the catheter shaft at the first end and the second end of the suction connector.

2. The system of claim 1, wherein the first end of the suction connector has a different configuration than the second end of the suction connector.

3. The system of claim 2, wherein the second end comprises a metal and the first end does not comprise a metal.

4. The system of claim 1, wherein the catheter shaft comprises one or more interference openings spaced apart from a proximal end of the catheter shaft configured to attach to the suction connector.

5. The system of claim 1, wherein a proximal end of the catheter shaft comprises a helically threaded interface.

6. The system of claim 2, wherein the second end of the suction connector comprises a helically threaded interface complementary to the helically threaded interface of the catheter shaft.

7. The system of claim 6, wherein the first end of the suction connector comprises is sized

to form a friction fit with the proximal end of the catheter shaft.

8. The system of claim 4, wherein the second end of the suction connector comprises a radially inward protrusion within the lumen and in the second end of the suction connector.

9. The system of claim 8, wherein the radially inward protrusion comprises a height orthogonal to the lumen, a leading surface and a trailing surface, where the leading surface is closer to a second opening of the second end than the trailing surface.

10. The system of claim 9, wherein the leading surface is angled away from the second opening.

11. The system of claim 10, wherein the leading surface comprises a first open angle that is greater than a second open angle of the trailing surface.

12. The system of claim 8, wherein the radially inward protrusion comprises a truncated shape, comprising a tip surface between the leading and trailing surfaces, wherein the tip surface comprises an angular orientation that is different from the leading surface and the trailing surface.

13. The system of claim 9, wherein the height of the radially inward protrusion is in a range of about 0.020 inches to about 0.035 inches.

14. The system of claim 11, wherein the first open angle is in the range of about 135 degrees to about 165 degrees.

15. The system of claim 14, wherein the second open angle is in the range of about 50 degrees to about 90 degrees.

16. The system of claim 1, wherein the suction catheter further comprises a suction control opening in communication with the lumen.

17. The system of claim 16, wherein the suction catheter further comprises a closure structure configured to reversibly close communication through the suction control opening and into the lumen.

18. The system of claim 17, wherein the closure structure comprises a tethered cap.

19. The system of claim 1, further comprising a suction guide comprising a lumen and configured to slidably couple to an endotracheal tube, wherein the lumen is configured to removably receive the catheter shaft.

20. The system of claim 19, wherein the suction guide, catheter shaft, and suction connector are provided in sealed packaging.

21. The system of claim 3, wherein the catheter shaft further comprises a tongue reinforcement member, the tongue reinforcement member comprising a proximal end, a distal end and a elongate body therebetween.

22. The system of claim 21, wherein the proximal end of the catheter shaft comprises a threaded metal annular body, and the proximal end of the tongue reinforcement member is attached to threaded metal annular body.

23. The system of claim 22, wherein the distal end of the tongue reinforcement member is located in the longitudinal lumen of the catheter shaft and is unattached to the catheter shaft.

24. The system of claim 22, wherein the distal end of the tongue reinforcement member is located 2 cm to 10 cm proximal to the distal end of the catheter shaft.

25. The system of claim 1, further comprising a suction guide configured to releasably and slidably couple to an endotracheal tube, and comprising an elongate lumen configured to receive the catheter shaft.

26. The system of claim 21, wherein the tongue reinforcement member is a metal wire.

27. The system of claim 1, further comprising:

a suction guide configured to slidably couple to an endotracheal tube;

wherein the suction guide, catheter shaft and suction connector are located in a sealed packaging.

28. The system of claim 27, further comprising one or more coupling members.

29. The system of claim 28, wherein the one or more coupling members is a clip, clamp, or adhesive tape.

30. The system of claim 27, wherein the suction connector is configured to releasably attach to the catheter shaft.

31. The system of claim 30, wherein the suction connector is pre-attached to the catheter shaft in the packaging.

32. The system of claim 27, wherein the catheter shaft is pre-inserted into the suction guide in the packaging.

33. A method of providing suction to an airway of a patient, comprising:

placing a suction guide device along an endotracheal tube inserted into an airway of a patient, wherein the endotracheal tube comprises a distal end and a proximal end;

advancing the suction guide along the endotracheal tube towards the distal end of the endotracheal tube;

positioning a catheter shaft at a location using the suction guide;

withdrawing the suction guide from the airway while maintaining the catheter shaft at the location; and

attaching a suction connector to the catheter shaft after withdrawing the delivery device from the airway.

34. The method of claim 33, wherein the suction connector is pre-attached to the catheter shaft and the method further comprises removing the suction connector from the catheter shaft before withdrawing the suction guide from the airway.

35. The method of claim 33, further comprising securing the catheter shaft to the endotracheal tube to resist displacement of the catheter shaft from the location after withdrawing the suction guide from the airway.

36. The method of claim 35, wherein securing the catheter shaft comprises coupling the suction catheter and endotracheal tube using a coupling member.

37. The method of claim 36, wherein the coupling member is a clip, clamp or adhesive tape.

38. The method of claim 33, wherein the suction connector is pre-attached to the catheter shaft at a first end of the suction connector.

39. The method of claim 38, wherein attaching the suction connector to the catheter shaft is performed using a second end of the suction connector.

40. The method of claim 38, wherein inserting the suction catheter is performed before advancing the delivery device along the endotracheal tube.

41. The method of claim 38, wherein inserting the suction catheter is performed after advancing the delivery device along the endotracheal tube.

42. The method of claim 33, wherein the suction catheter is pre-inserted into the lumen of the delivery device at the point of manufacture.

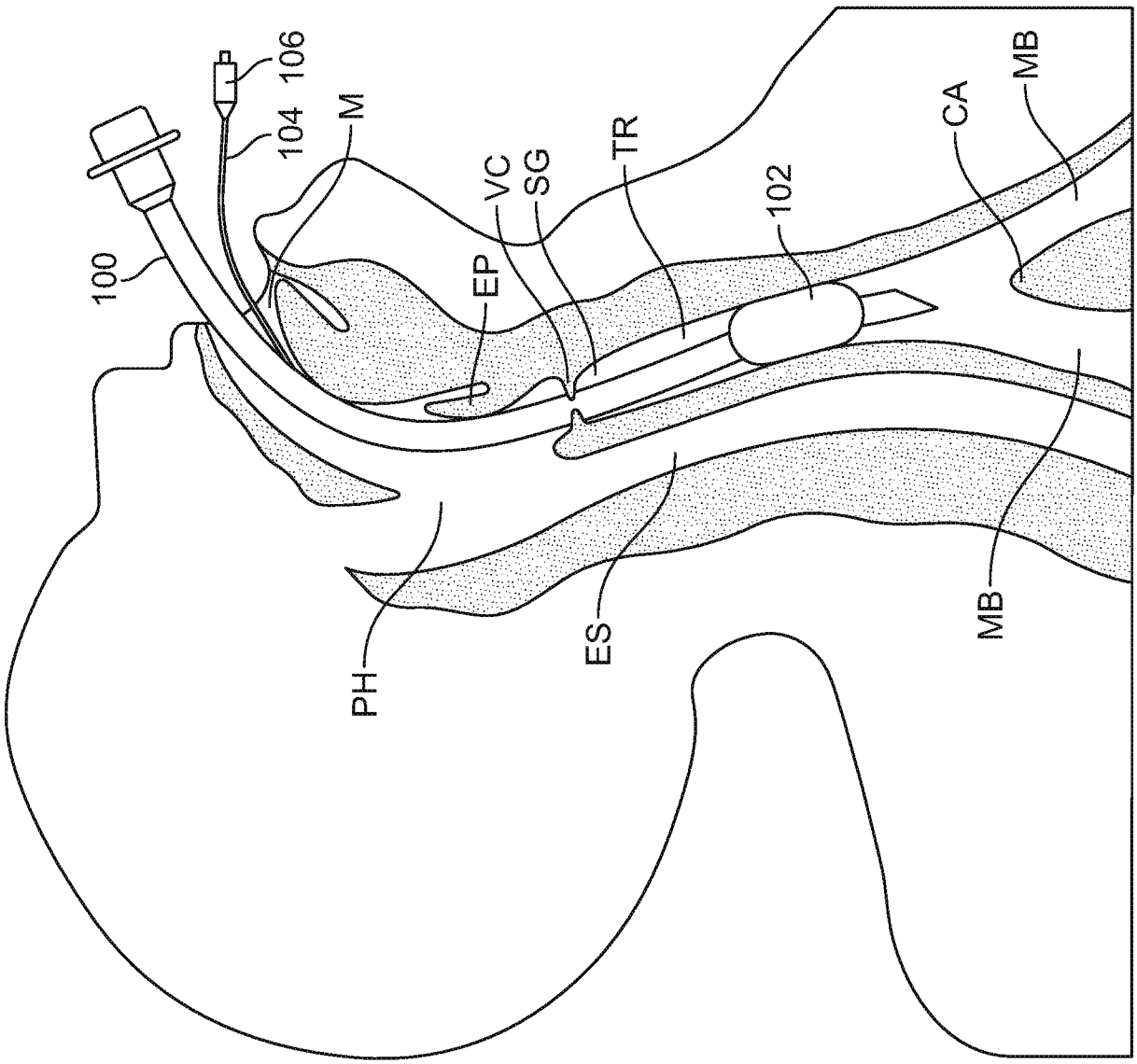


FIG. 1

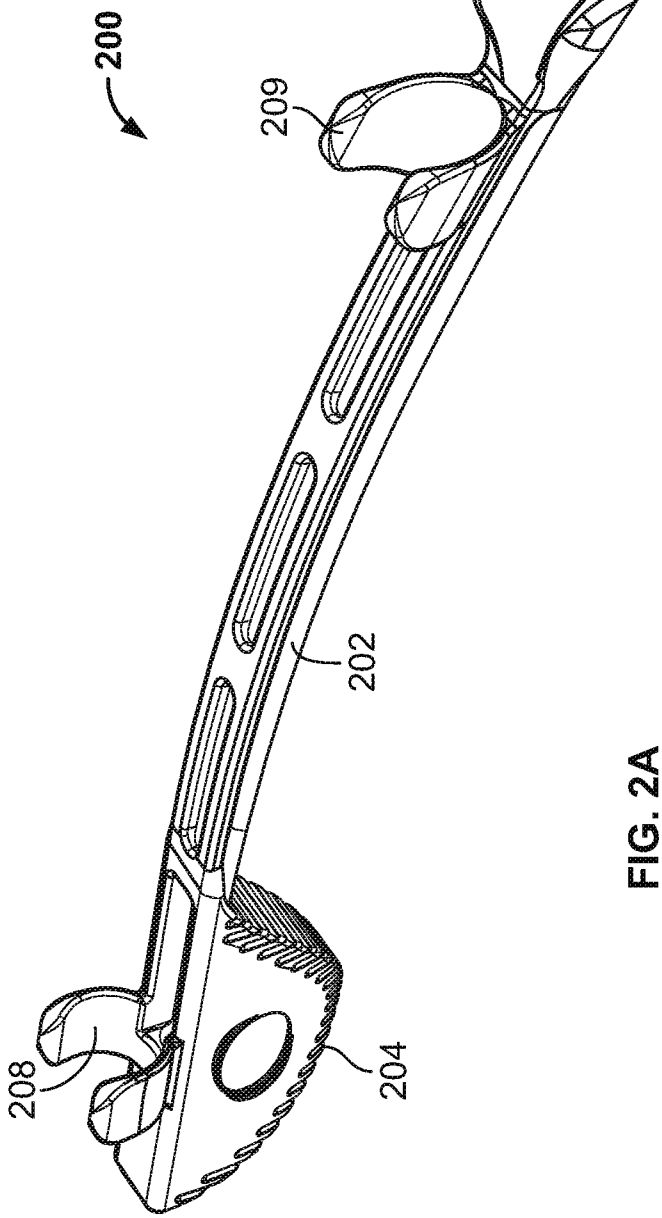


FIG. 2A

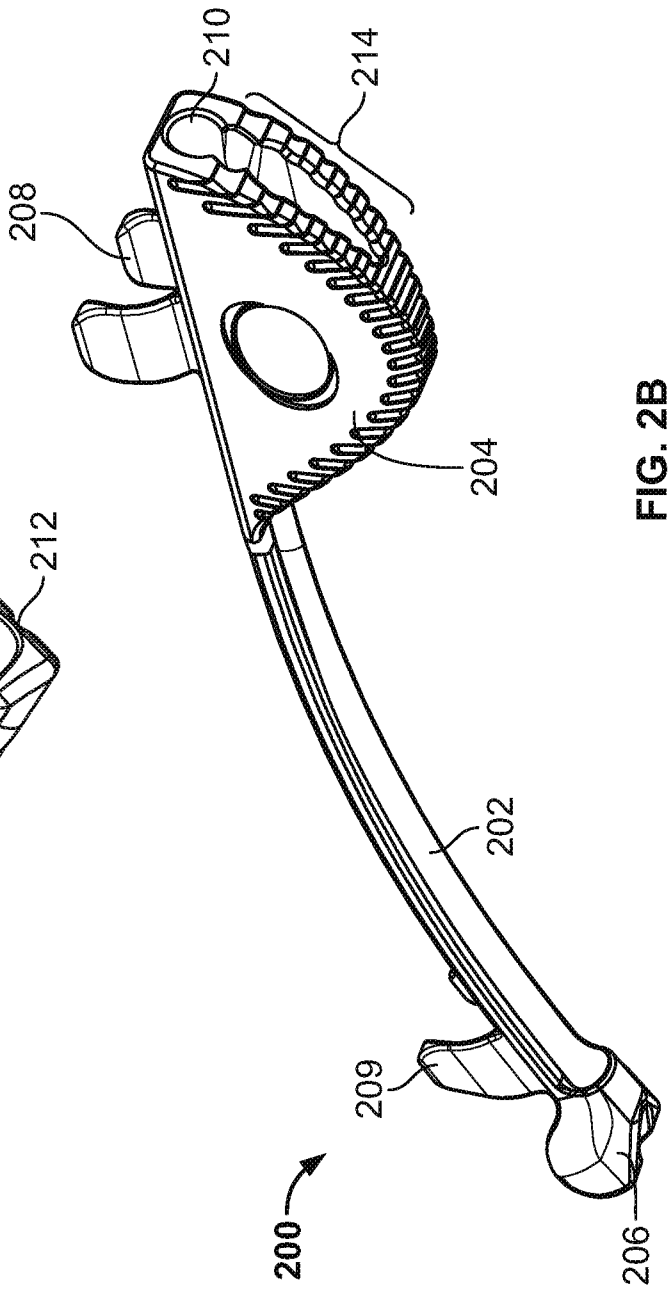


FIG. 2B

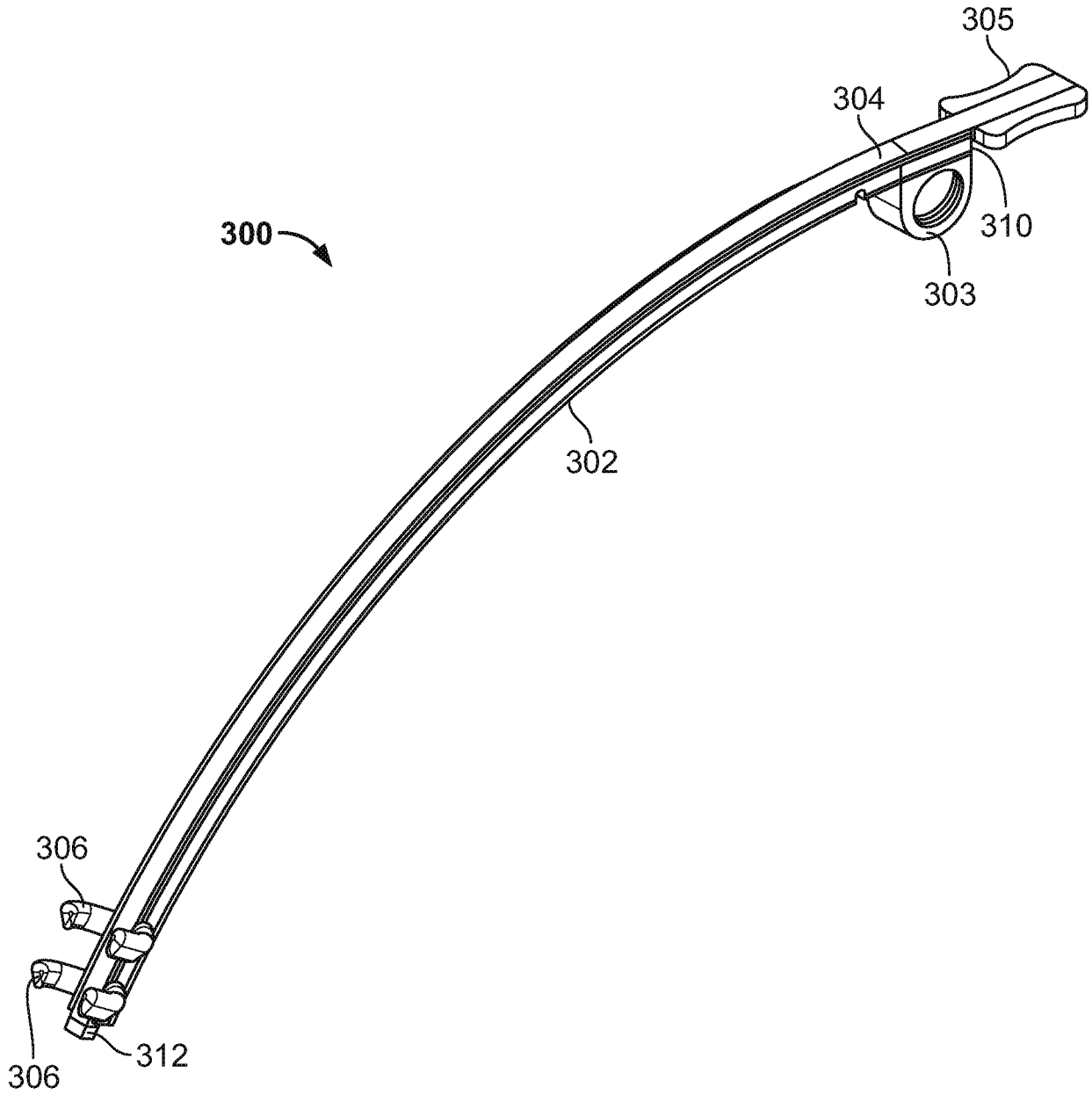


FIG. 3A

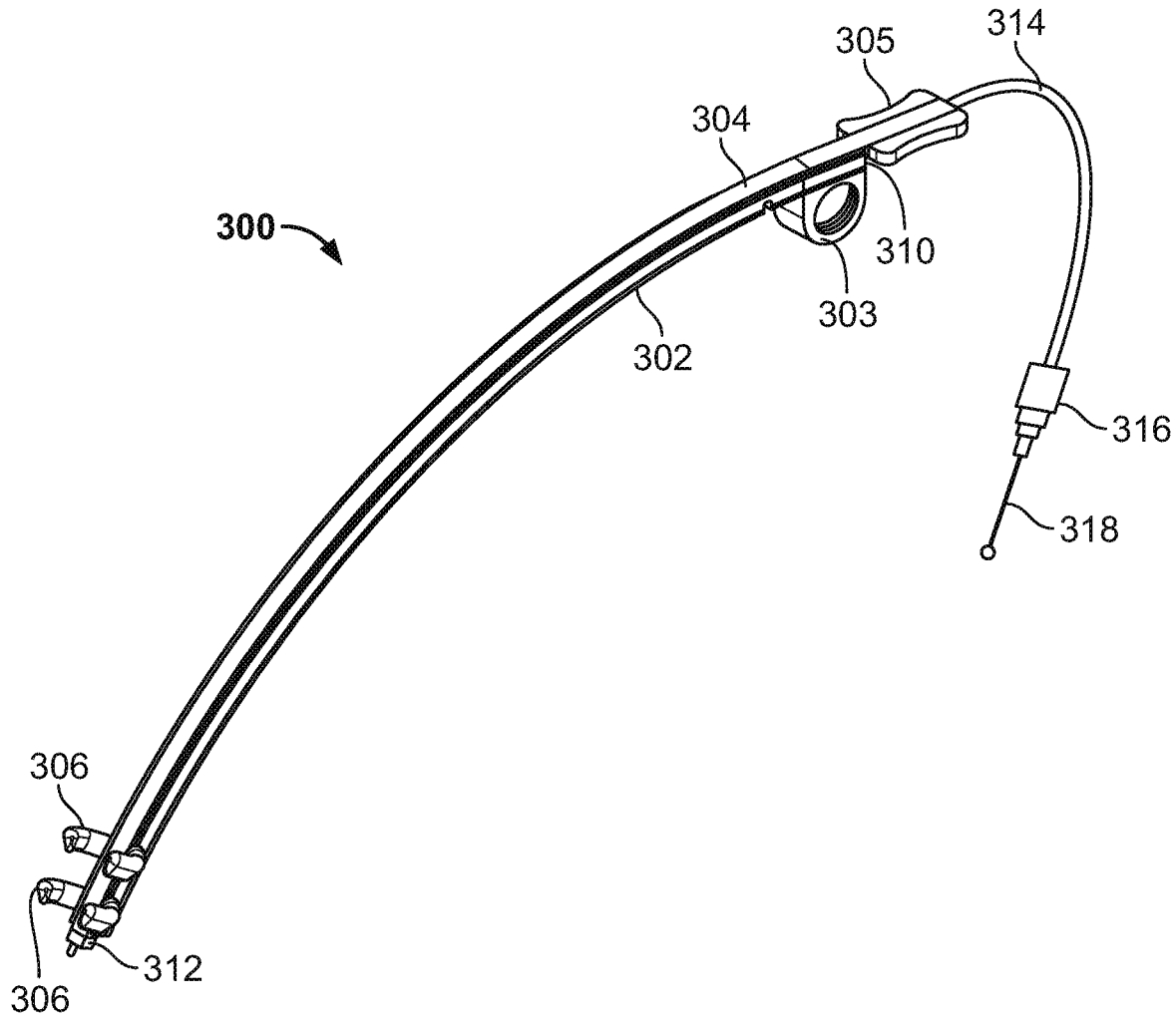


FIG. 3B

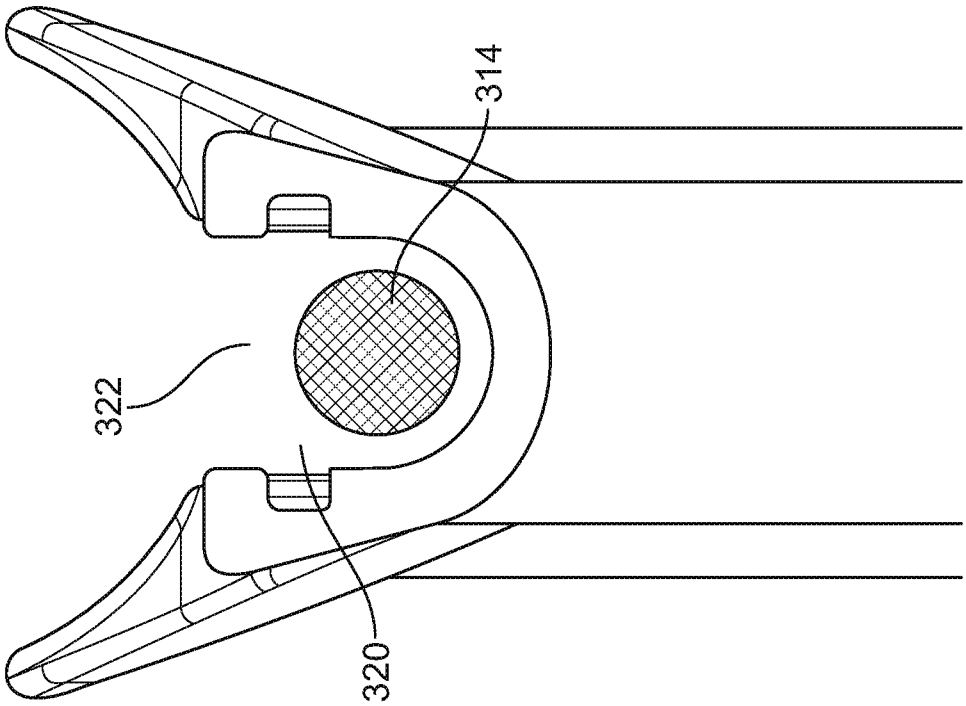


FIG. 3D

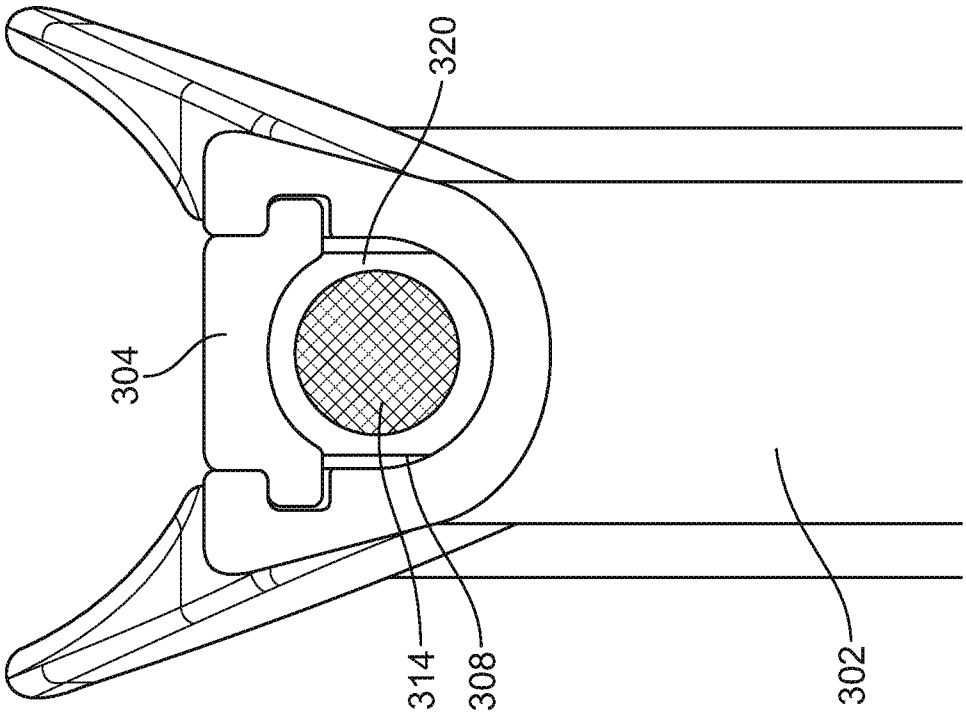


FIG. 3C

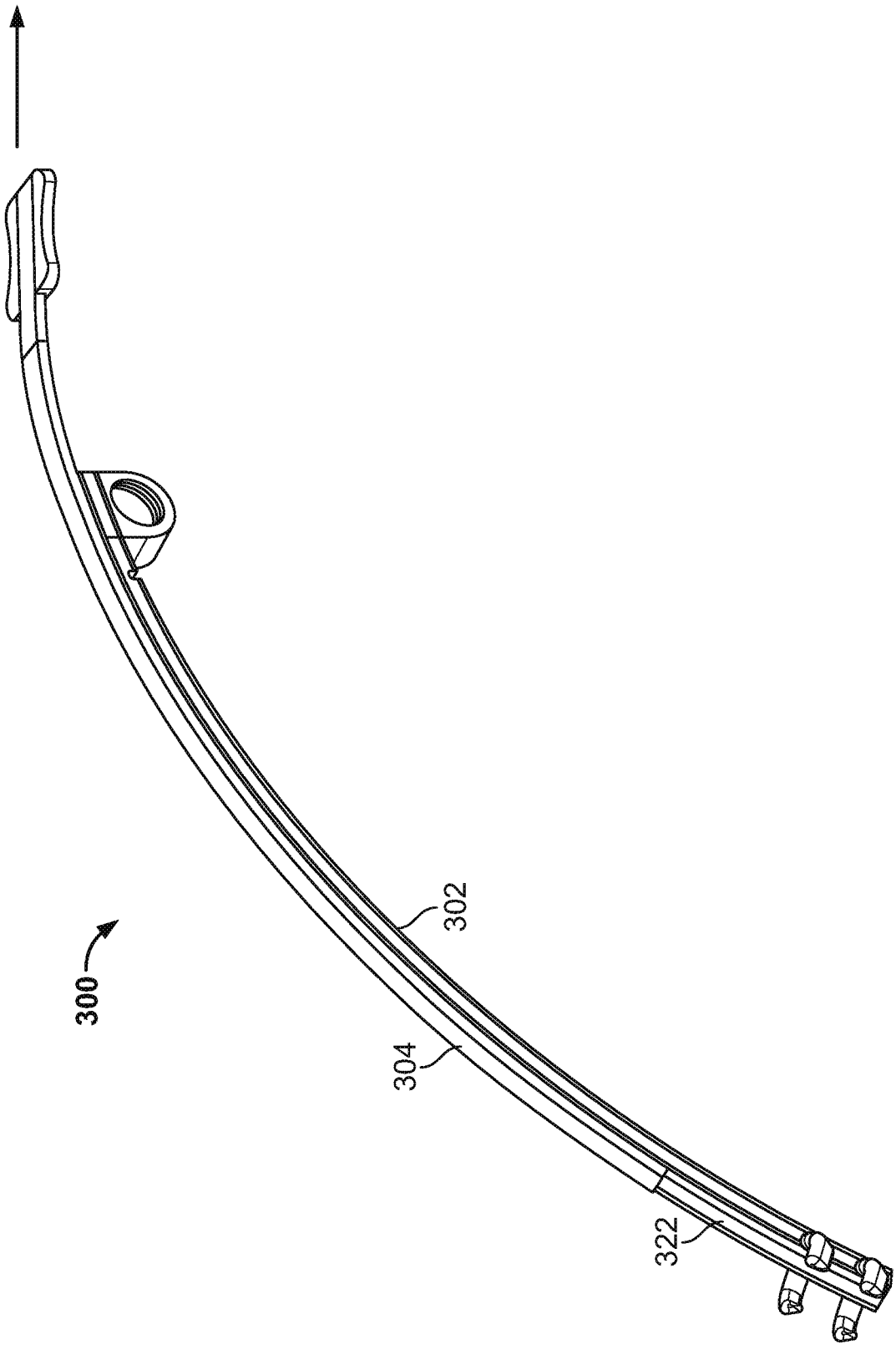


FIG. 3E

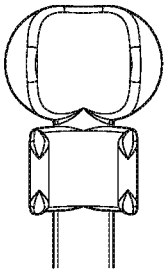


FIG. 4A

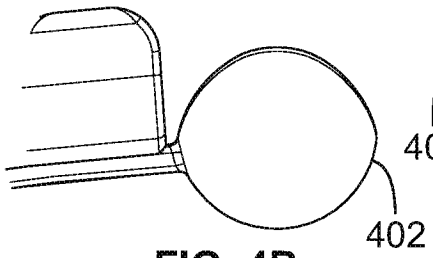


FIG. 4B

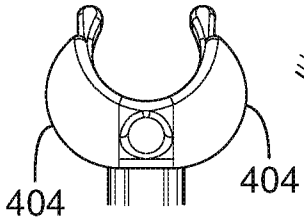


FIG. 4C

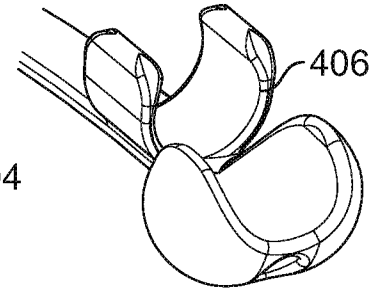


FIG. 4D

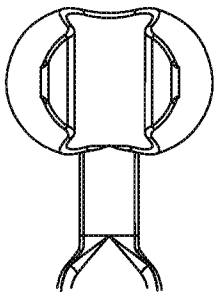


FIG. 5A

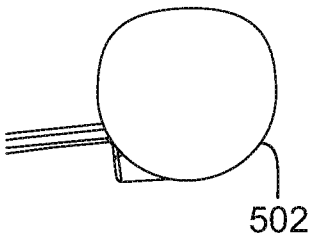


FIG. 5B

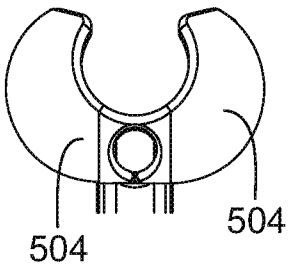


FIG. 5C

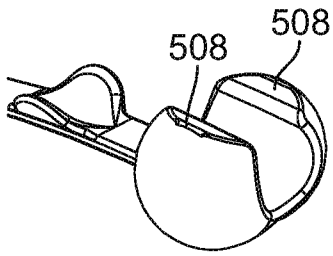


FIG. 5D

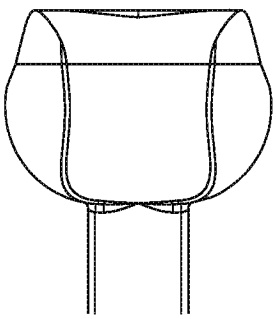


FIG. 6A

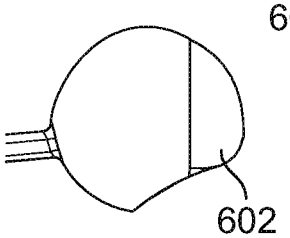


FIG. 6B

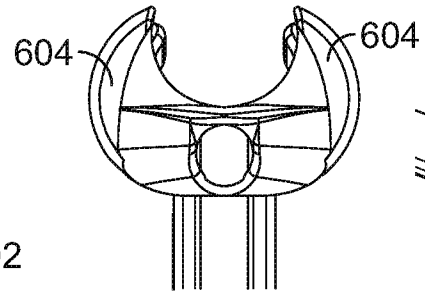


FIG. 6C

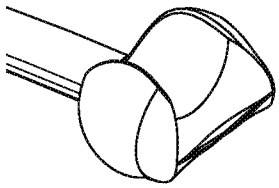


FIG. 6D

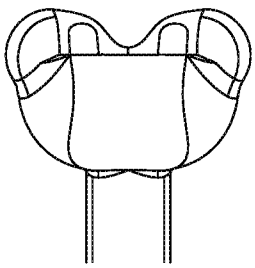


FIG. 7A

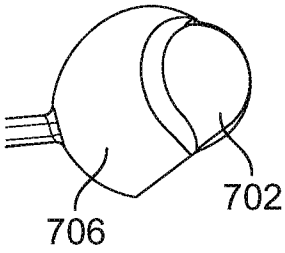


FIG. 7B

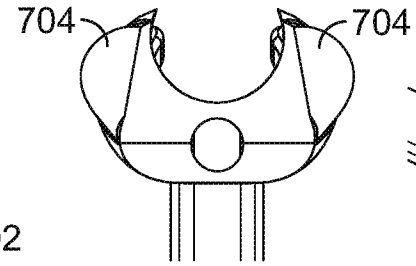


FIG. 7C

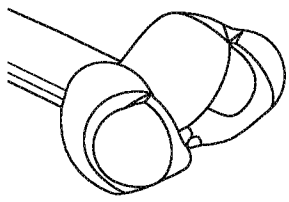


FIG. 7D

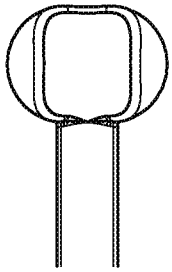


FIG. 8A

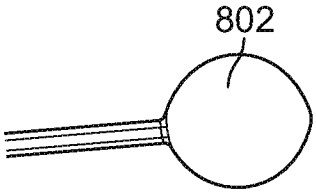


FIG. 8B

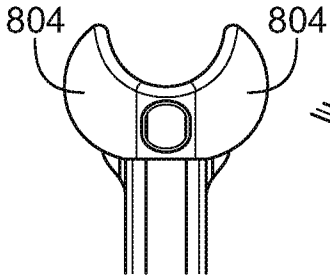


FIG. 8C

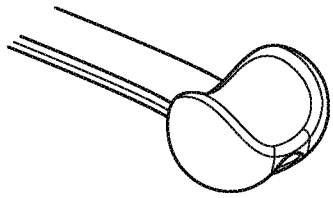


FIG. 8D

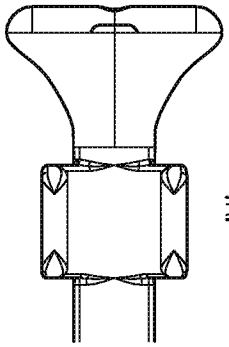


FIG. 9A

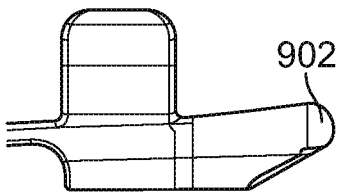


FIG. 9B

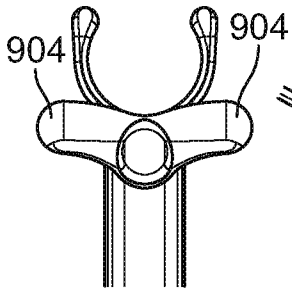


FIG. 9C

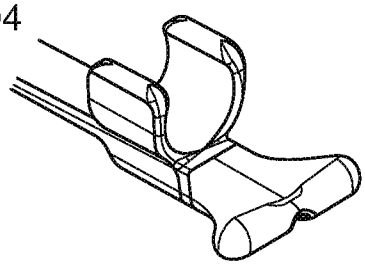


FIG. 9D

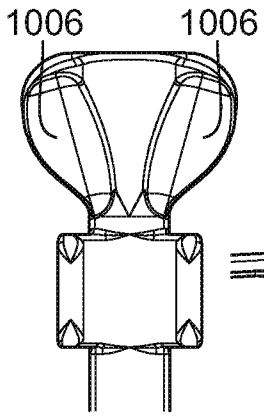


FIG. 10A

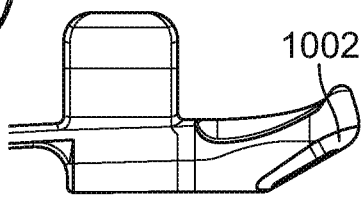


FIG. 10B

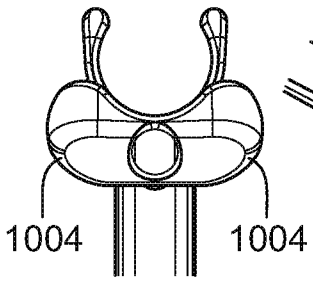


FIG. 10C

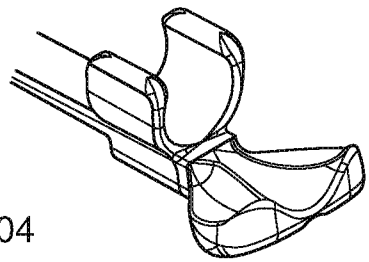


FIG. 10D

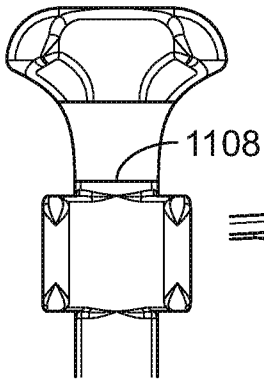


FIG. 11A

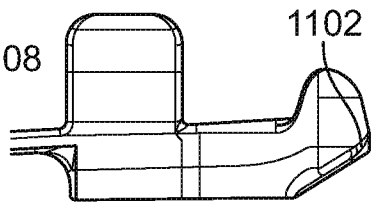


FIG. 11B

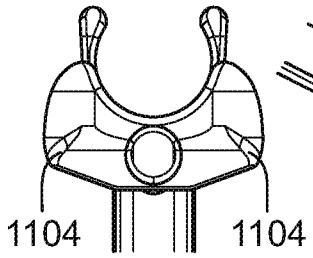


FIG. 11C

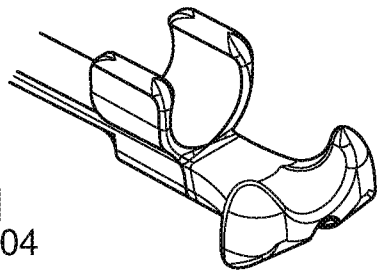


FIG. 11D

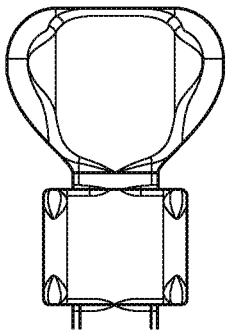


FIG. 12A

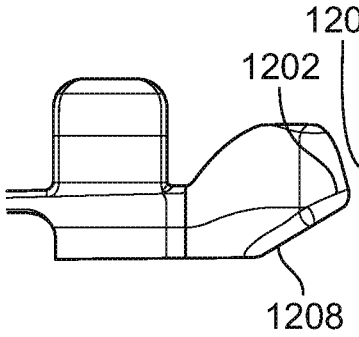


FIG. 12B

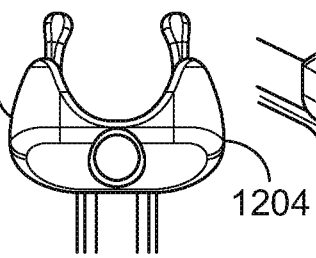


FIG. 12C

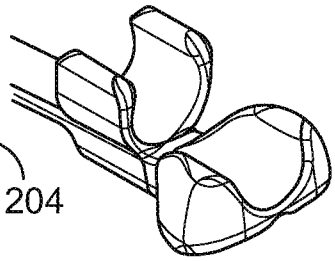


FIG. 12D

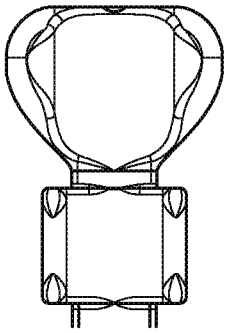


FIG. 13A

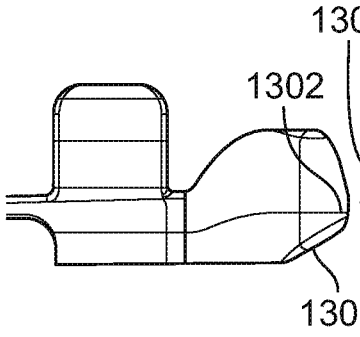


FIG. 13B

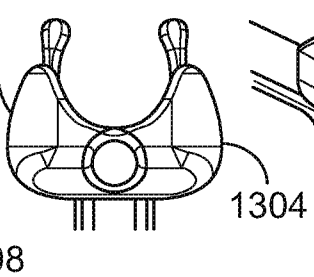


FIG. 13C

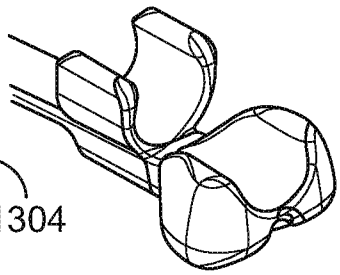


FIG. 13D

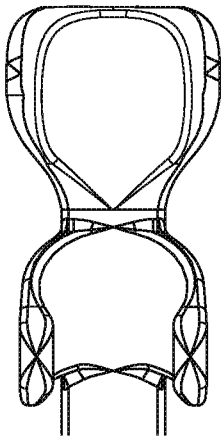


FIG. 14A

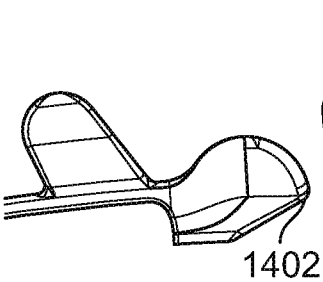


FIG. 14B

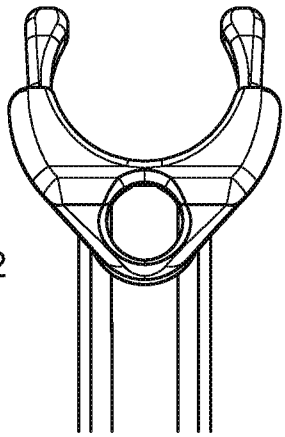


FIG. 14C

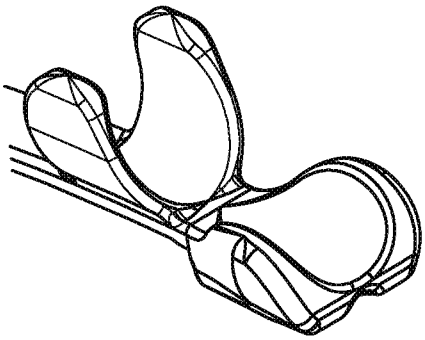


FIG. 14D

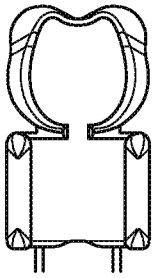


FIG. 15A

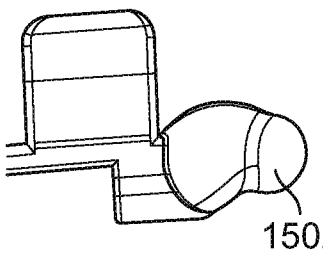


FIG. 15B

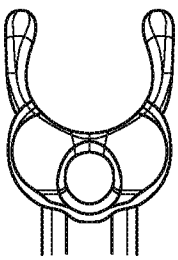


FIG. 15C

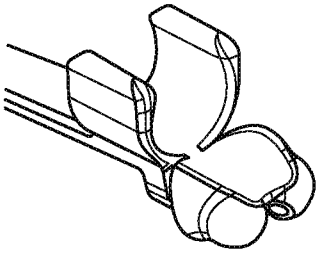


FIG. 15D

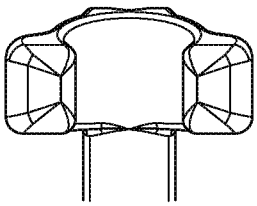


FIG. 16A

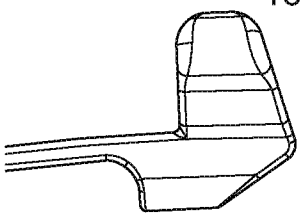


FIG. 16B

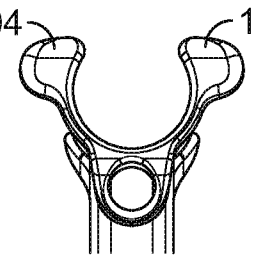


FIG. 16C

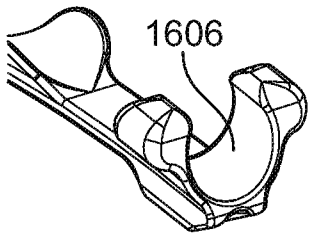


FIG. 16D

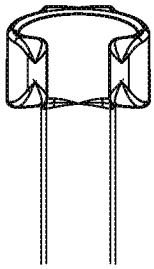


FIG. 17A

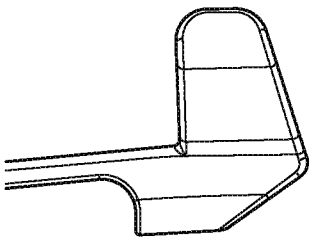


FIG. 17B

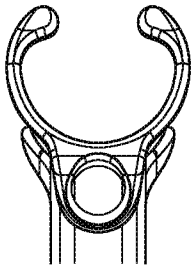


FIG. 17C

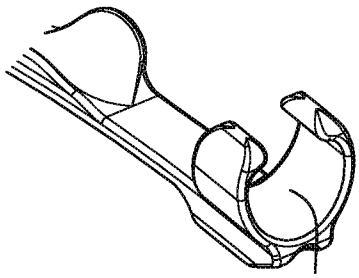


FIG. 17D

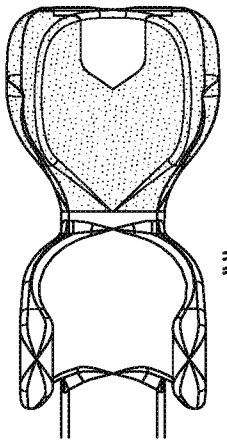


FIG. 18A

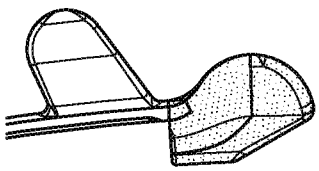


FIG. 18B

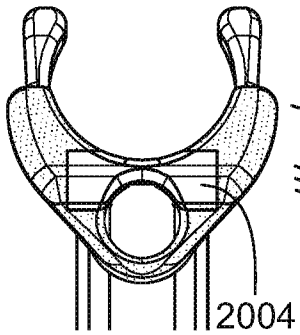


FIG. 18C

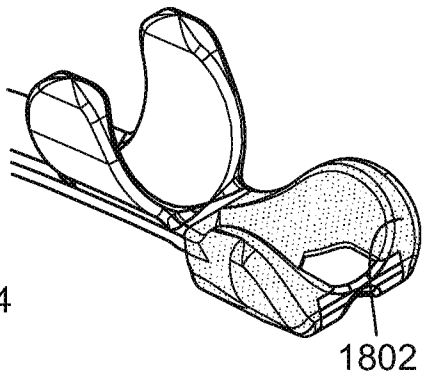


FIG. 18D

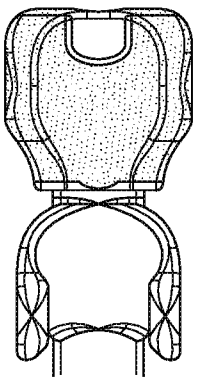


FIG. 19A

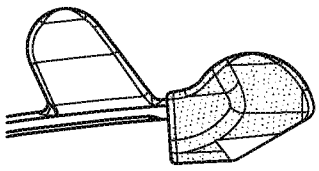


FIG. 19B

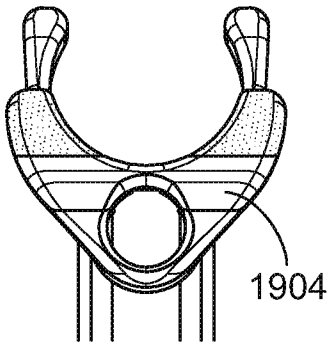


FIG. 19C

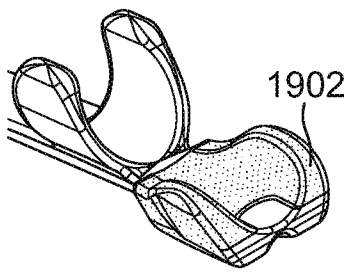


FIG. 19D

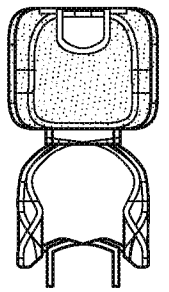


FIG. 20A

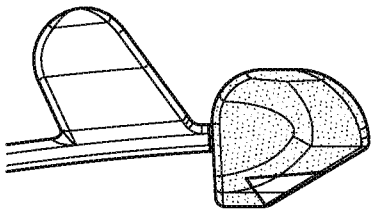


FIG. 20B

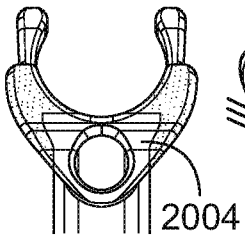


FIG. 20C

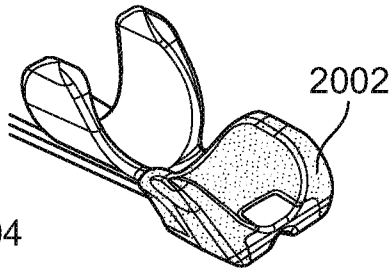


FIG. 20D

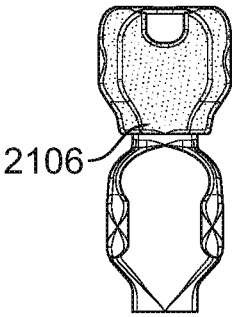


FIG. 21A

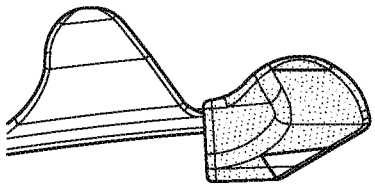


FIG. 21B

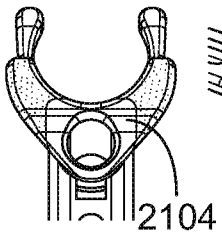


FIG. 21C

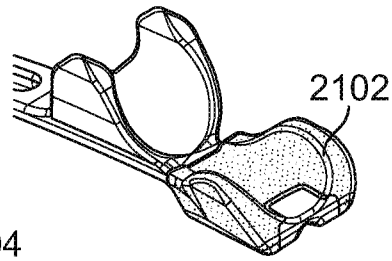


FIG. 21D

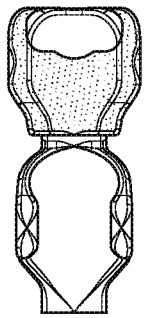


FIG. 22A

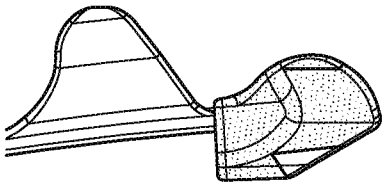


FIG. 22B

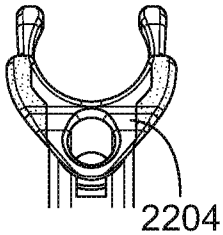


FIG. 22C

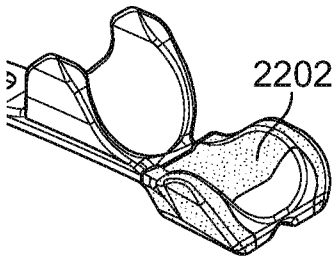


FIG. 22D

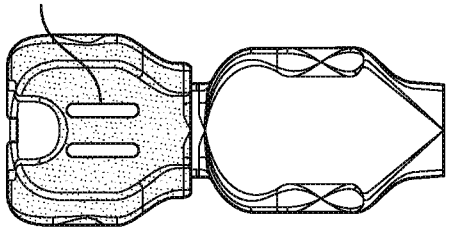


FIG. 23A

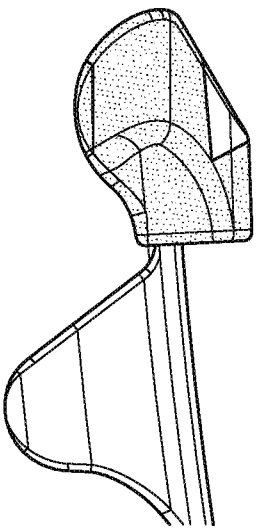


FIG. 23B

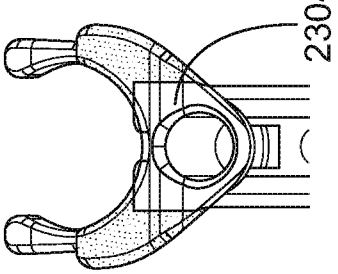


FIG. 23C

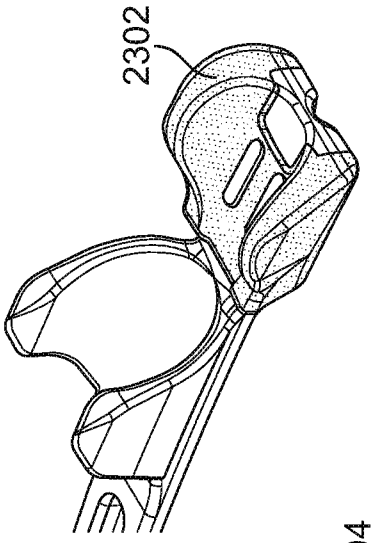


FIG. 23D

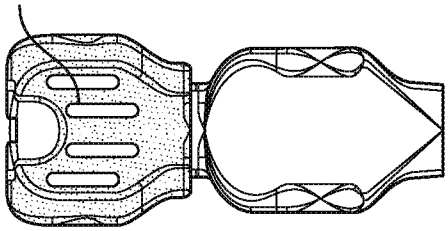


FIG. 24A

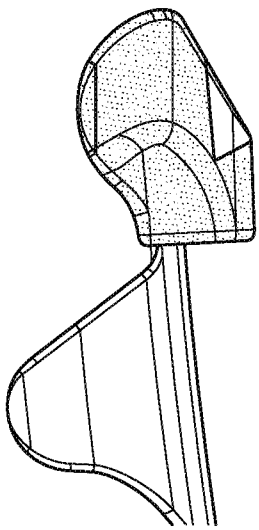


FIG. 24B

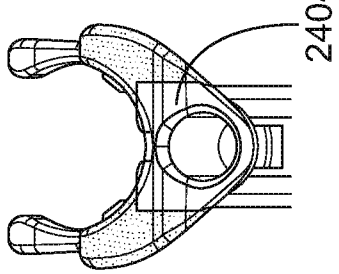


FIG. 24C

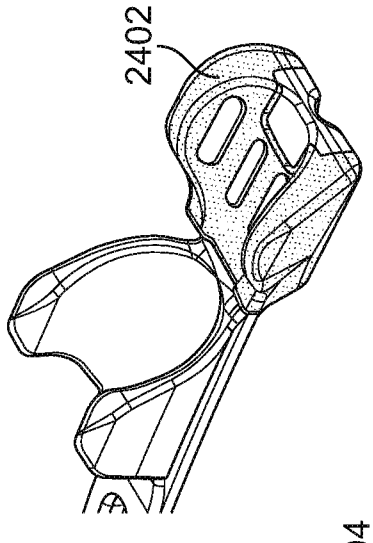


FIG. 24D

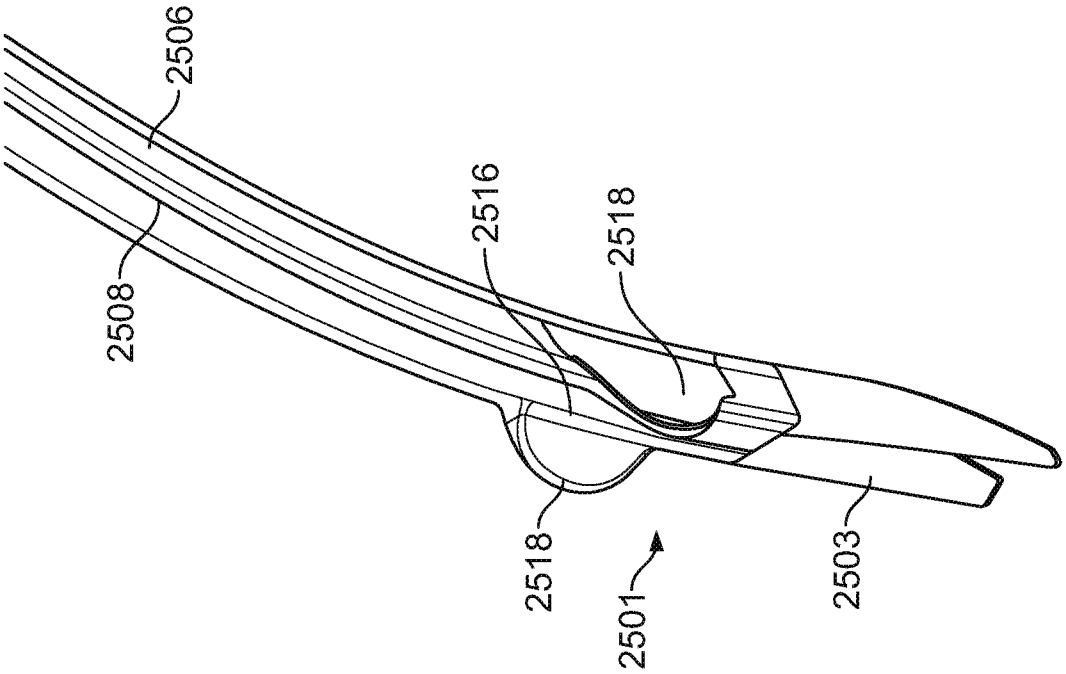


FIG. 25B

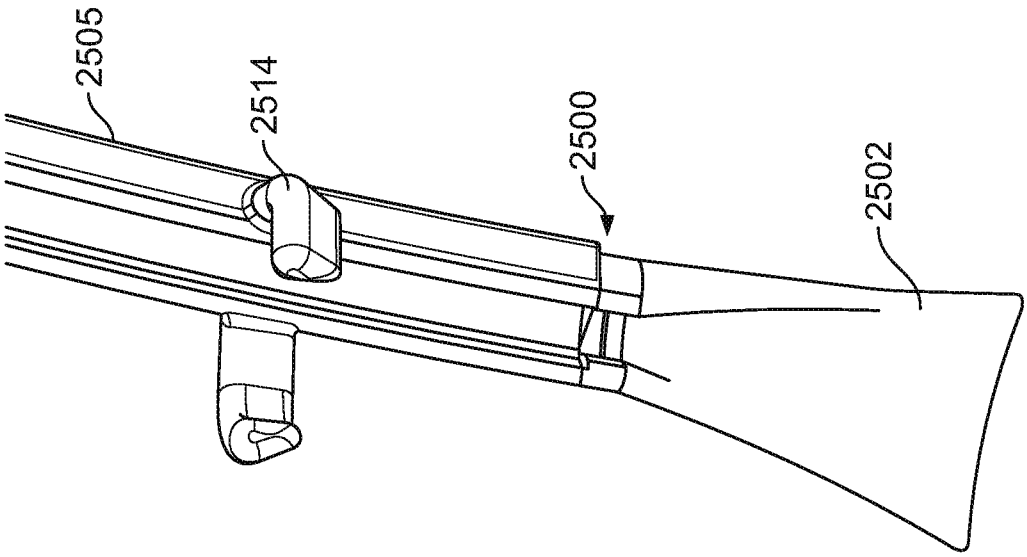


FIG. 25A

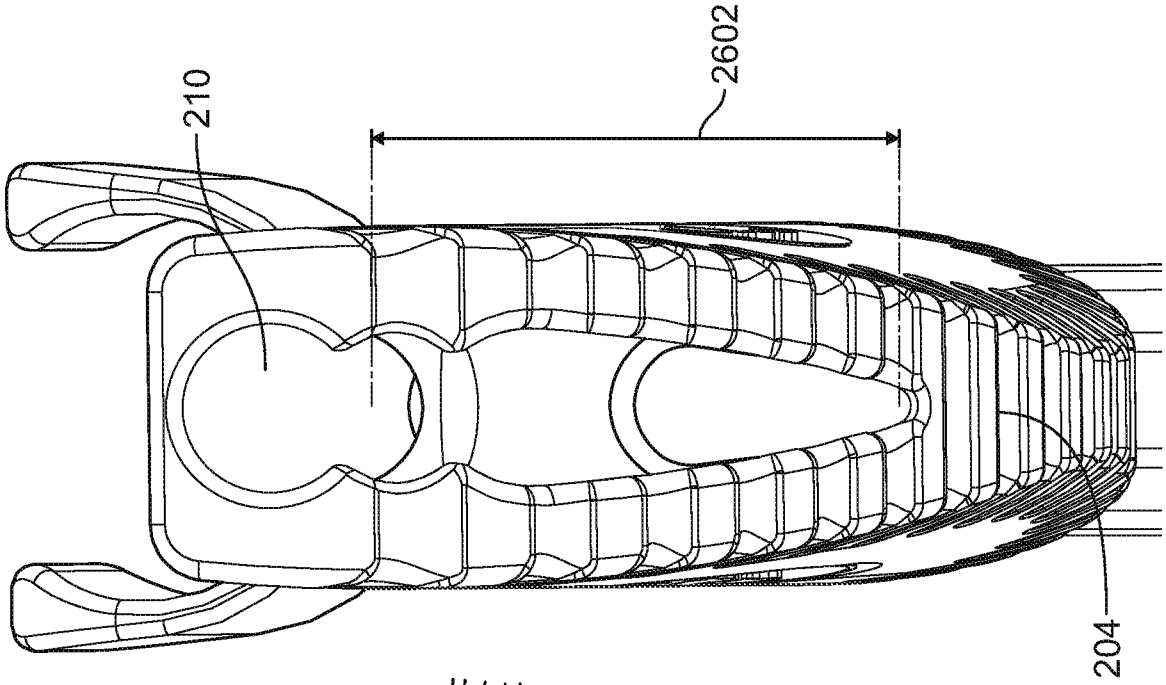


FIG. 26B

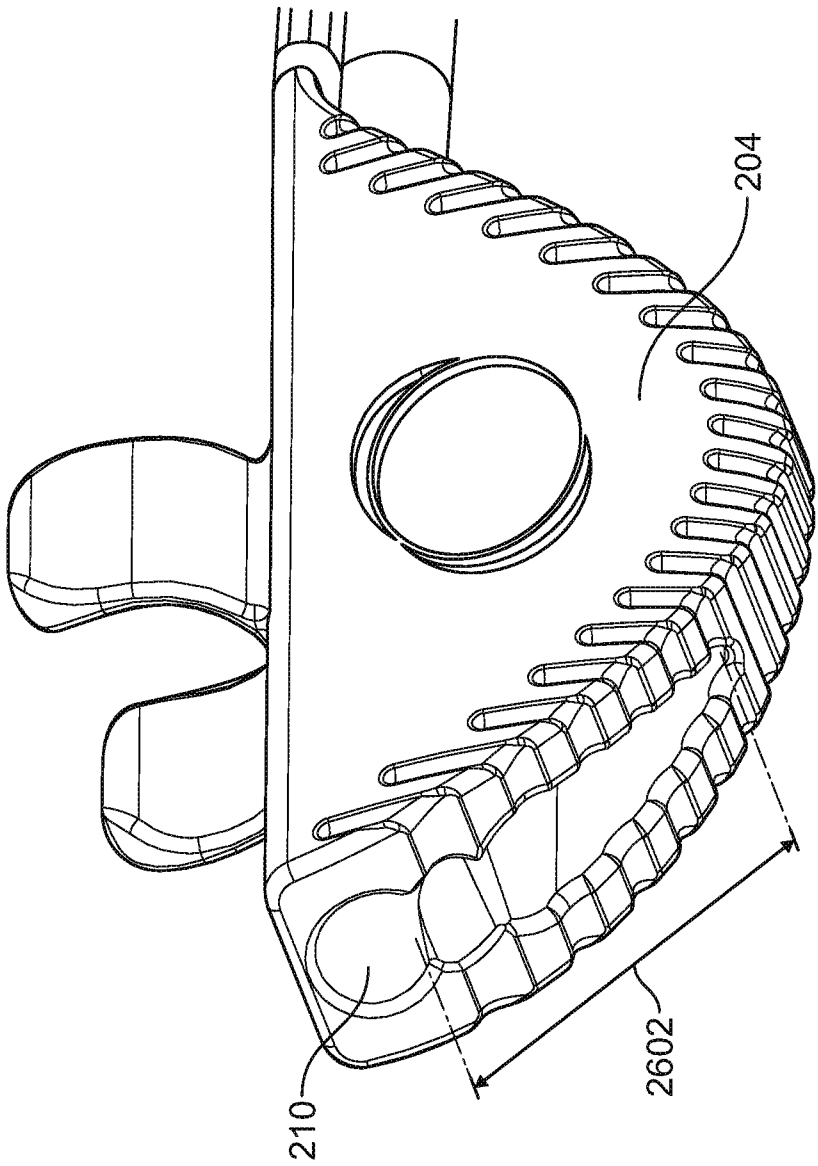


FIG. 26A

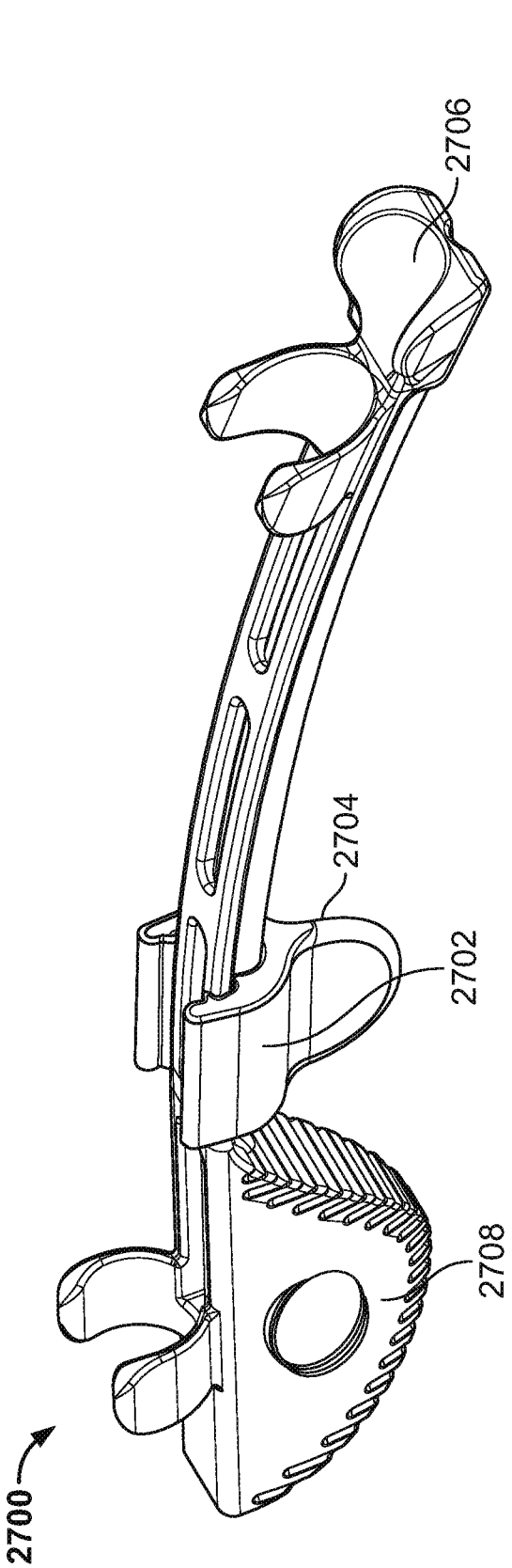


FIG. 27A

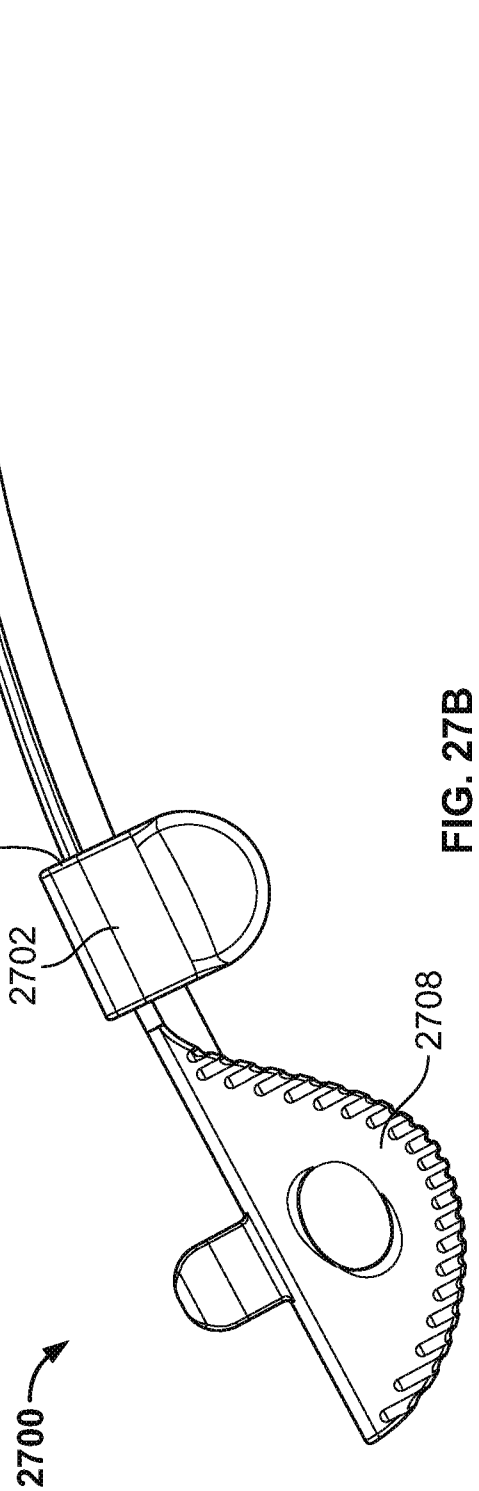


FIG. 27B

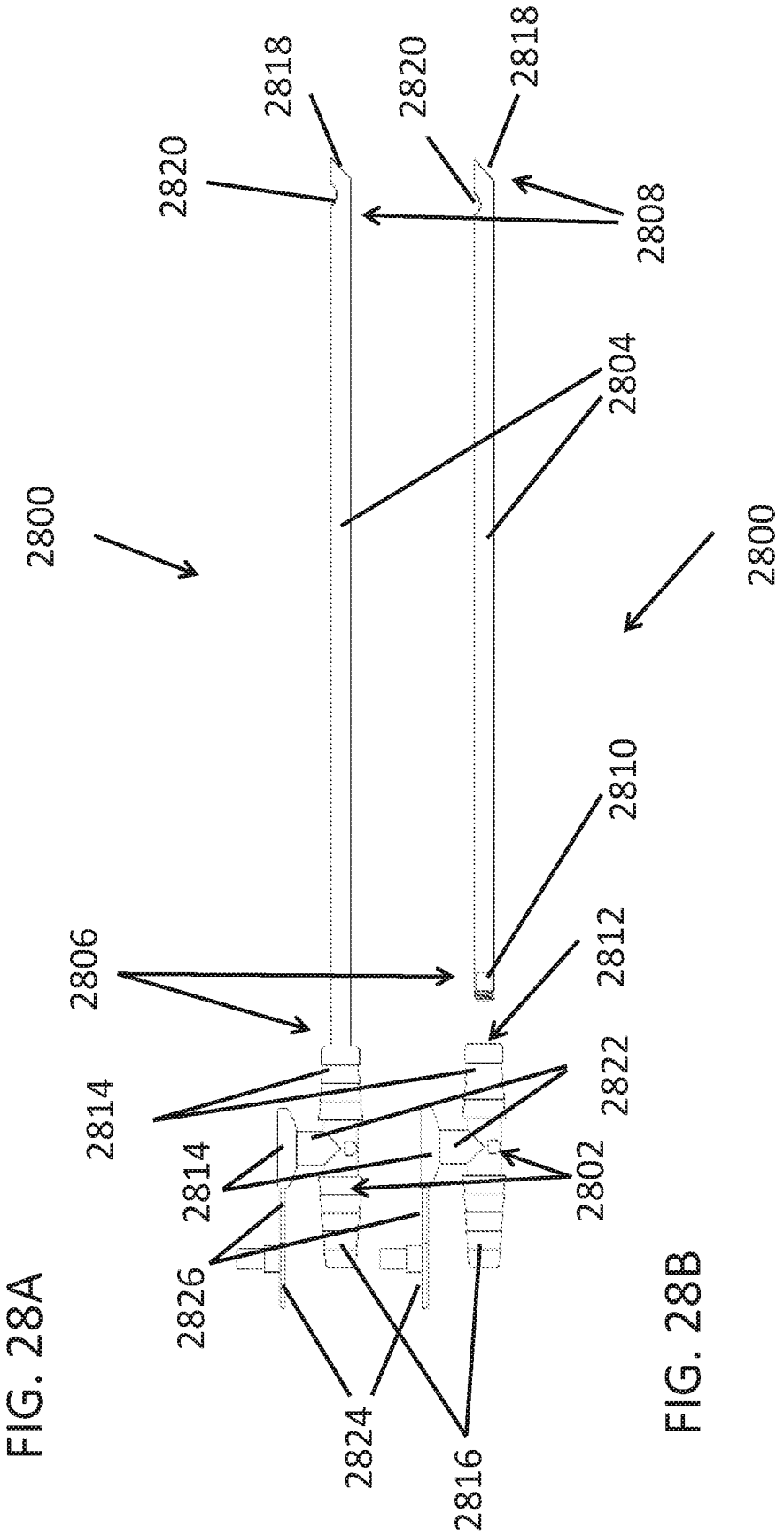


FIG. 28A

FIG. 28B

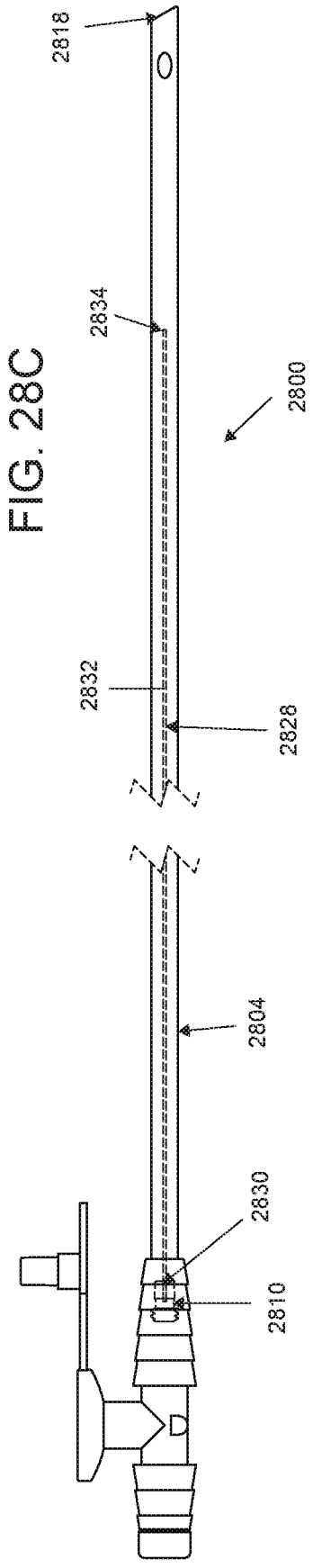


FIG. 28C

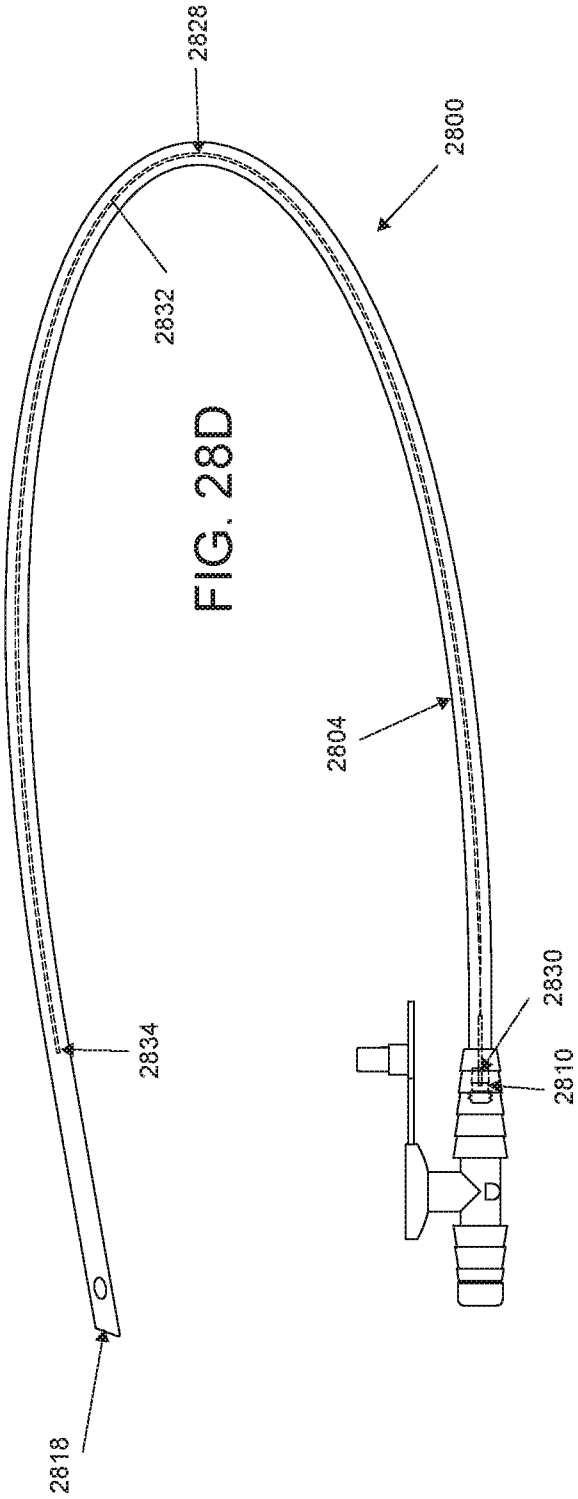


FIG. 28D

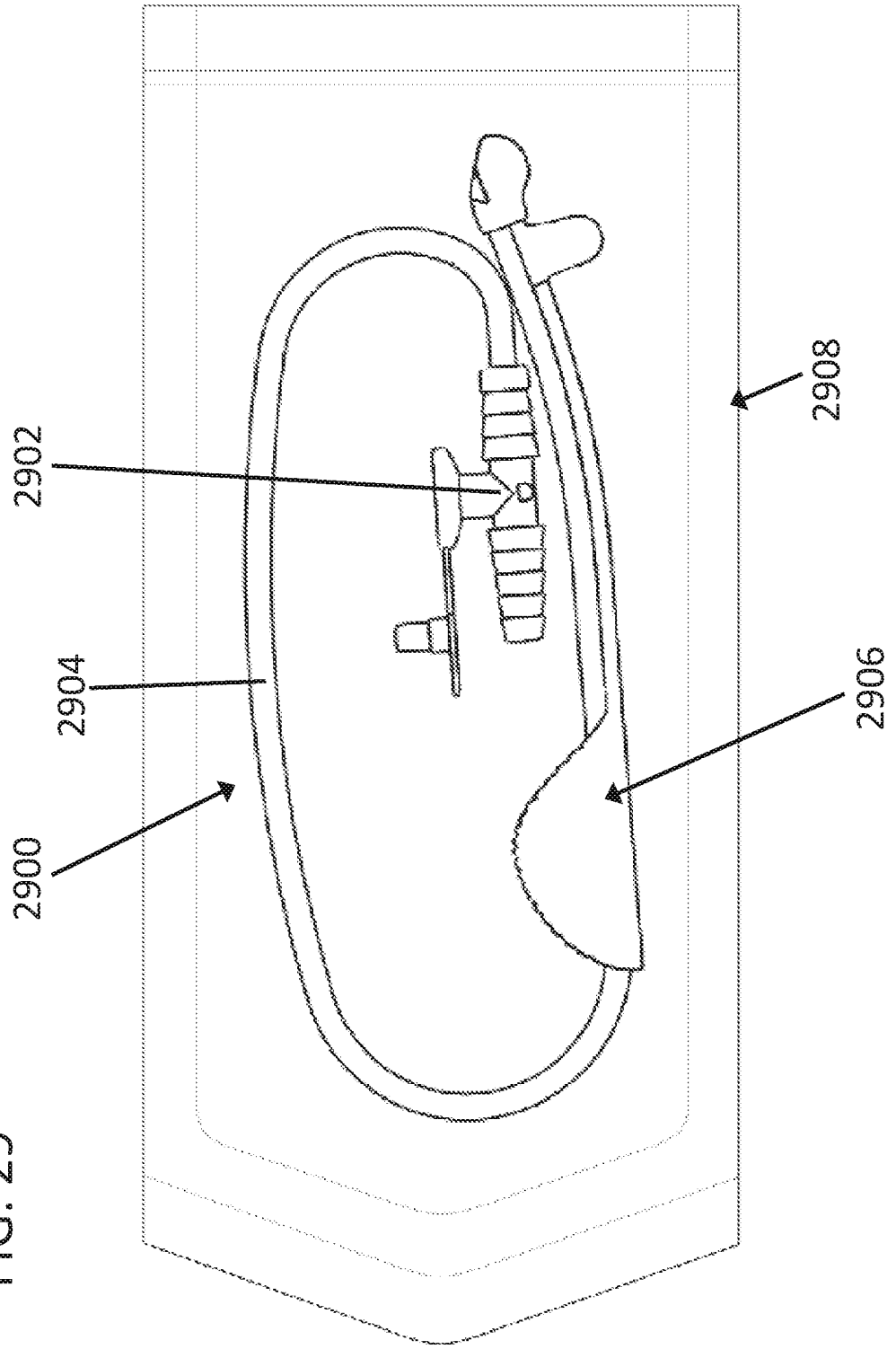


FIG. 29

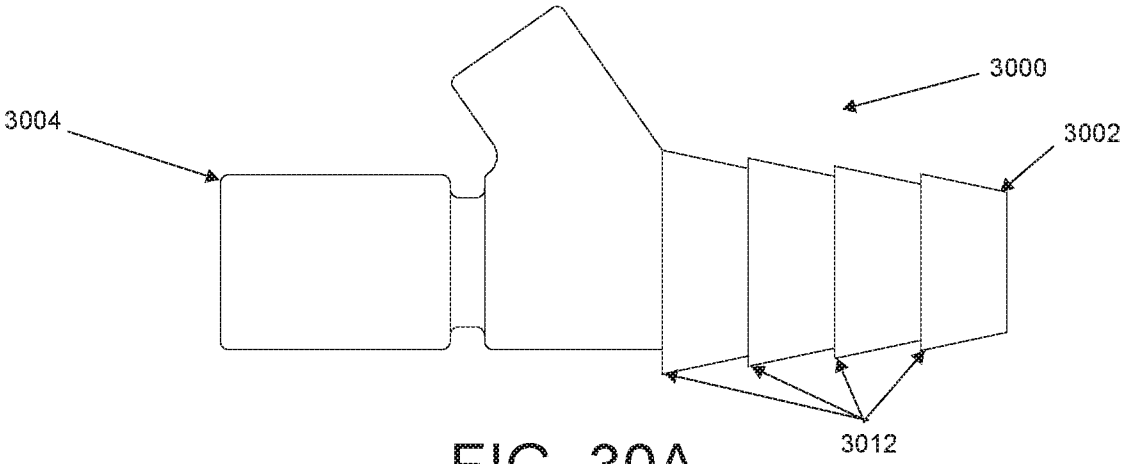


FIG. 30A

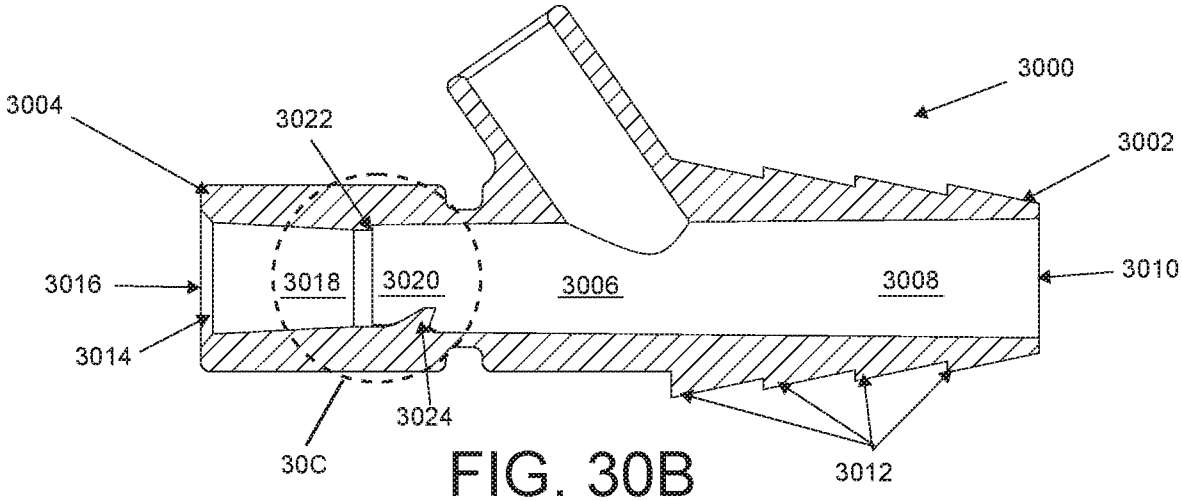


FIG. 30B

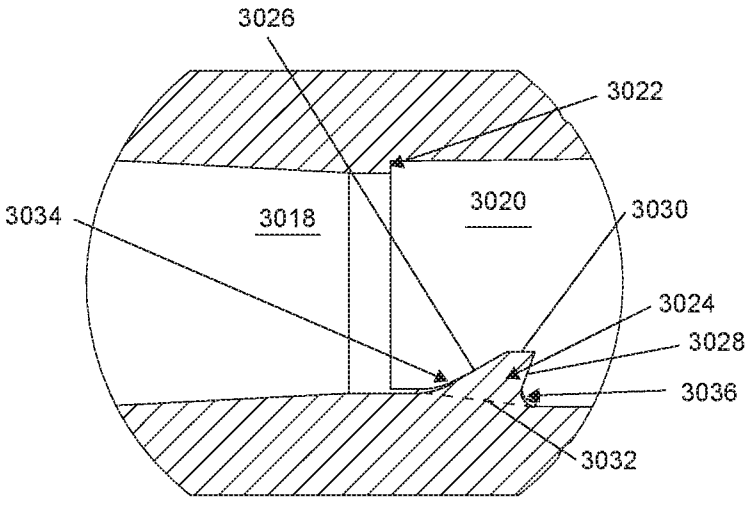


FIG. 30C

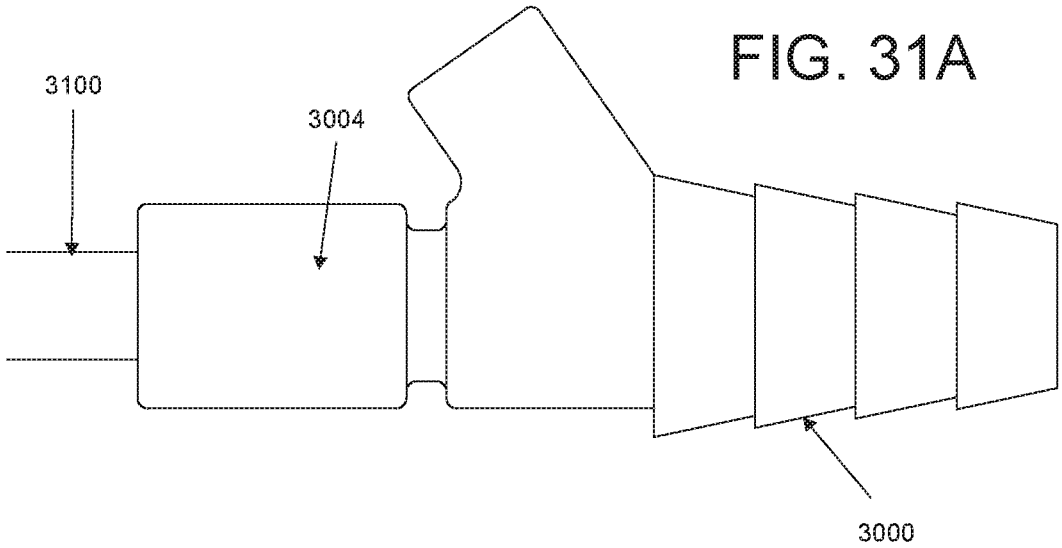


FIG. 31A

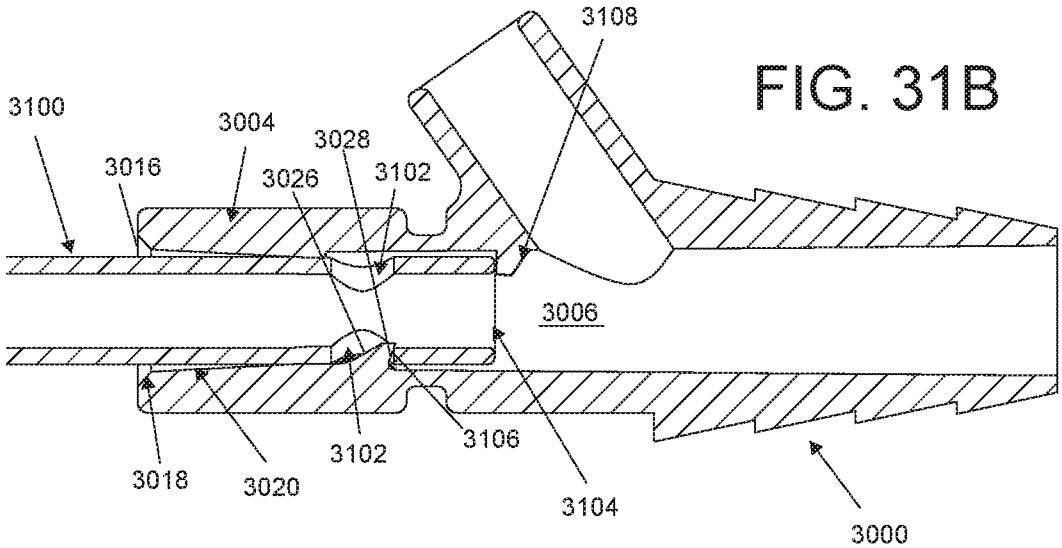


FIG. 31B

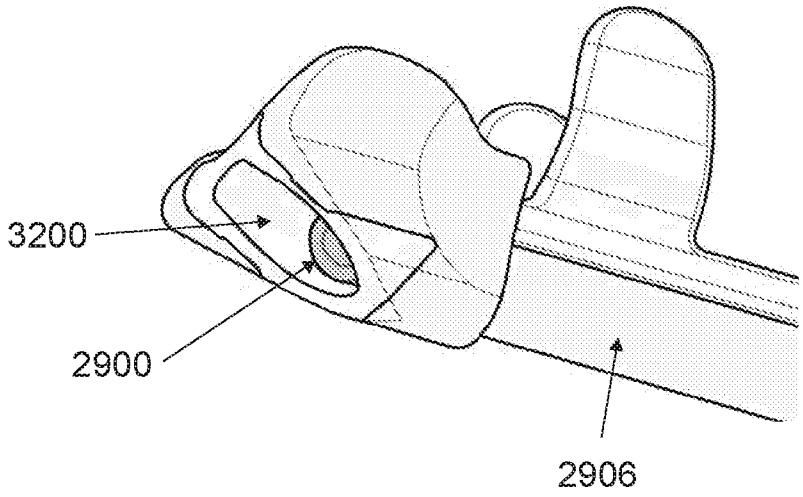


FIG. 32

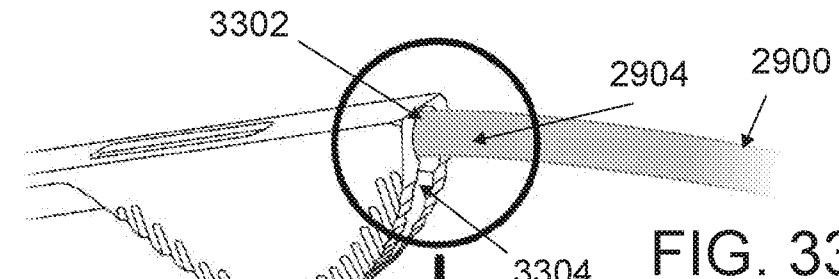


FIG. 33A

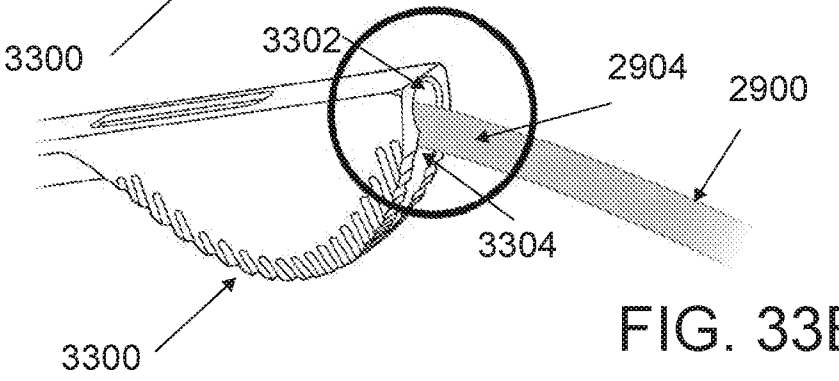


FIG. 33B

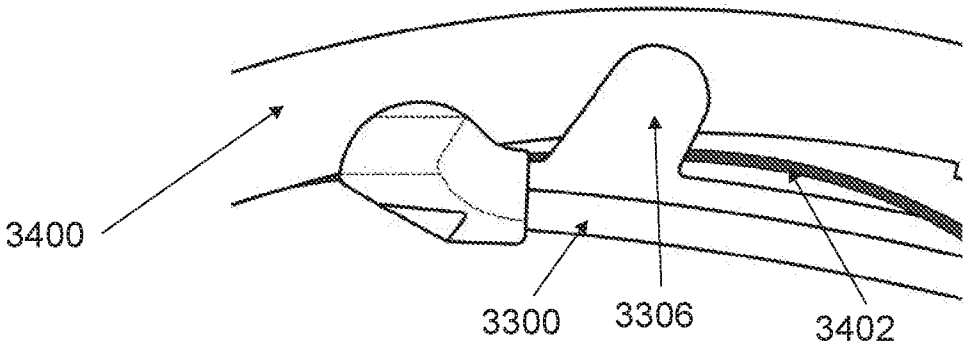


FIG. 34

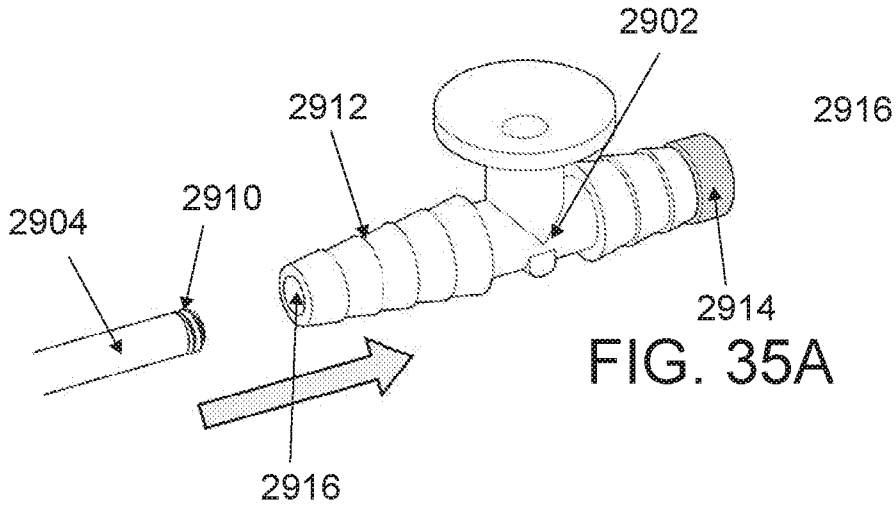


FIG. 35A

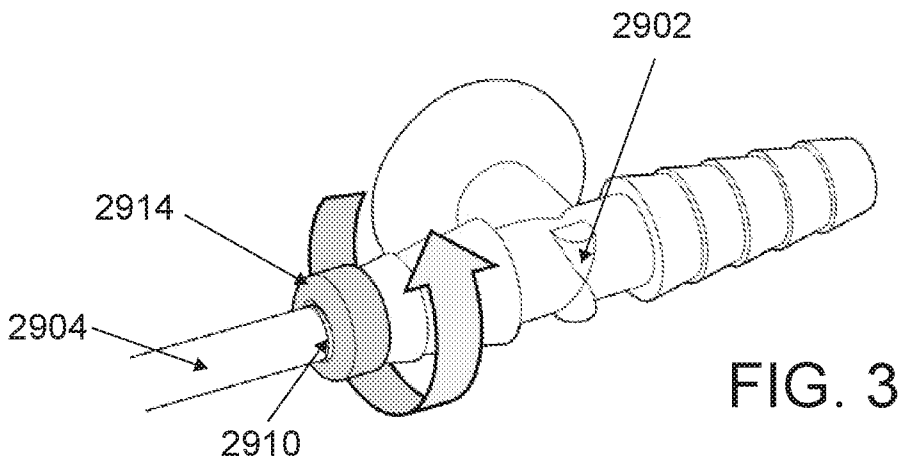


FIG. 35B

FIG. 36A

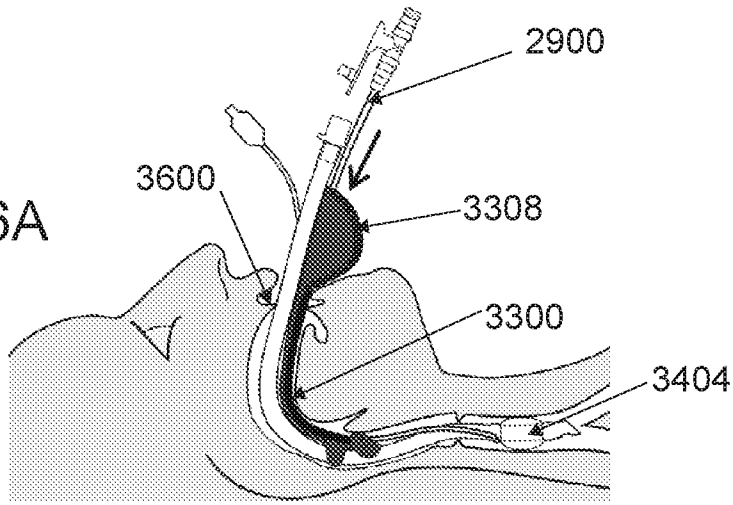


FIG. 36B

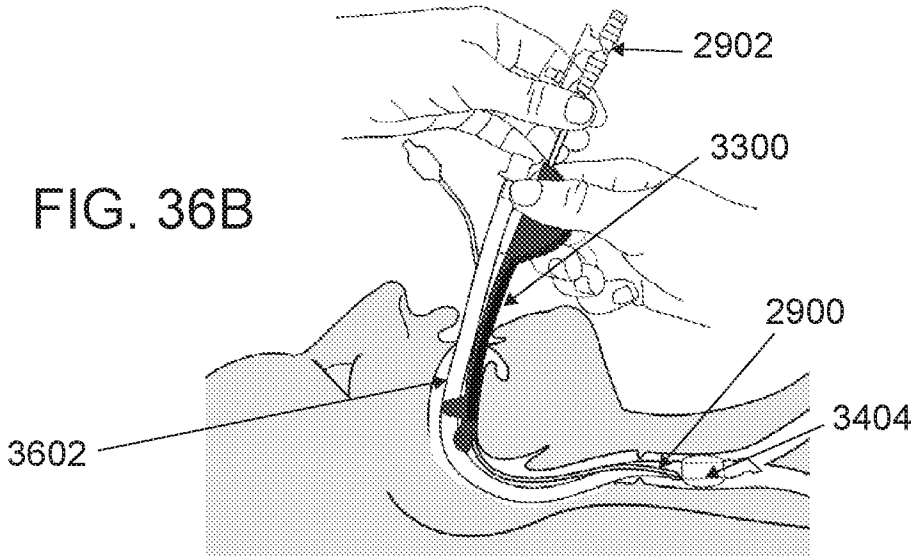
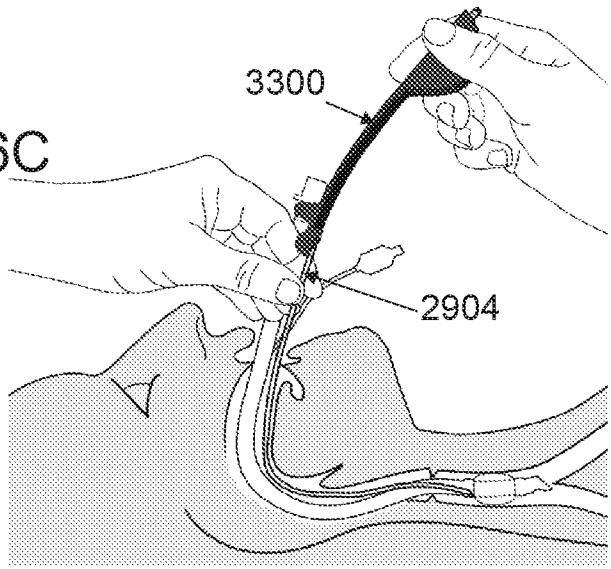


FIG. 36C



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029303

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 1/04; A61M 16/04; A61M 16/08; A61M 25/01; A61M 25/06 (2017.01)

CPC - A61M 1/008; A61M 16/04; A61M 16/0463; A61M 16/0488; A61M 25/0102; A61M 25/0662 (2017.05)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 137/381; 600/188; 604/35; 604/43; 604/119 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,167,622 A (MUTO) 01 December 1992 (01.12.1992) entire document	1-3, 6, 7, 16 --- 5, 17, 18
X	US 2015/0141942 A1 (CIEL MEDICAL INC) 21 May 2015 (21.05.2015) entire document	1, 19, 20, 25, 27-33, 35-41
Y	US 5,409,470 A (MCINTYRE et al) 25 April 1995 (25.04.1995) entire document	5
Y	US 6,070,582 A (KEE) 06 June 2000 (06.06.2000) entire document	17, 18
A	US 5,601,537 A (FRASSICA) 11 February 1997 (11.02.1997) entire document	1-42
A	US 5,738,091 A (KEE et al) 14 April 1998 (14.04.1998) entire document	1-42
A	US 5,337,780 A (KEE) 16 August 1994 (16.08.1994) entire document	1-42

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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

"E" earlier application or patent but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2017	06 JUL 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774