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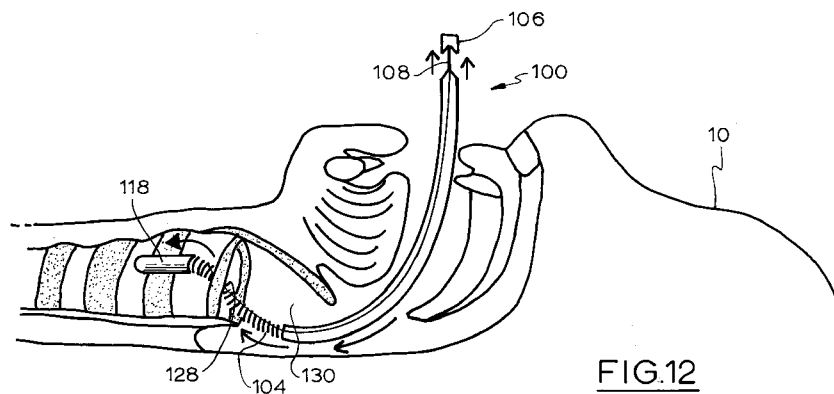


FIG. 12

(57) Abstract: A device to facilitate an intubation procedure, such as placement of an endotracheal tube. The device includes a shaft having a wall with a flexible region proximate a tip of the shaft. The shaft both distally and proximally of the flexible region is of a higher durometer than the durometer of the flexible region. A cord extending along the shaft is used to move the tip away from the longitudinal axis of the shaft.

SYSTEM AND METHOD FOR FACILITATING AN INTUBATION

Field of the Invention

[0001] The present invention relates to improvements in devices designed to facilitate an intubation procedure, such as placement of an endotracheal tube.

Background of the Invention

[0002] Endotracheal intubation is a core technique in anaesthesia (and critical care medicine). It is the gold standard method to provide oxygenation and ventilation to a patient under general anaesthesia. It requires the passage of an endotracheal tube (ETT) through the vocal cords into the trachea.

[0003] The primary and traditional method of endotracheal intubation involves direct laryngoscopy with a laryngoscope. The laryngoscope has a gently curved blade which is passed into the mouth and sits in the oropharynx to provide a direct line of sight to the vocal cords. Most patients can be successfully intubated using this technique; however circumstances where this is difficult or impossible occur relatively regularly in anaesthesia (6%) and other areas of critical care (16%).

[0004] Difficult intubation has the potential to result in great patient harm from inadequate oxygenation causing death, brain damage and/or heart attacks. Difficult intubation requiring multiple or repeated attempts can also result in trauma to the airway. Management of these scenarios has been and continues to be a major focus in anaesthesia and critical care medicine. This has resulted in multiple "airway" management strategies and the development of improved equipment.

[0005] Although there can be a variety of causes that result in a difficult intubation, ultimately there are two main factors that are responsible:

Difficulty in visualising the vocal cords and/or

Difficulty in directing an ETT through the vocal cords into the trachea.

[0006] These two factors are generally managed by using a videolaryngoscope (to improve visualisation of the vocal cords) and/or a specialised ETT introducer (to guide the ETT through the vocal cords). However both of these techniques have limitations which can still result in a difficult or failed intubation for various reasons detailed below.

[0007] For the first factor, difficult visualisation, direct laryngoscopy relies on achieving a “line of sight” to directly visualise the vocal cords from the mouth and provide a pathway to pass the ETT. Certain patient factors or abnormal upper airway anatomy can make this “line of sight” difficult to achieve, and hence the intubation difficult. In current anaesthetic practice, this situation is most likely to be managed with a videolaryngoscope (VLS). This technology incorporates a light source and optical capabilities onto the tip of a modified laryngoscope. An image is produced that can be visualised on a separate monitor. This technique is called “indirect” laryngoscopy because it does not require a direct “line of sight” to visualise the vocal cords from the mouth. It can greatly improve the visualisation of the vocal cords in most patients with a difficult intubation. Many of the devices have a sharply angled curve on their VLS blade designed for abnormal airway anatomy. This effectively allows the anaesthetist to “see around corners” and has been an extremely valuable advancement in airway management.

[0008] For the second factor, difficulty in directing the ETT, successful intubation requires the ETT to travel along the pathway between the mouth and vocal cords into the trachea.

[0009] Referring to Fig. 1, good visualisation of the vocal cords during traditional direct laryngoscopy generally implies that there is a shallow (gently curved) pathway for the ETT to follow within the oropharynx and that intubation will be easy. This however may not be the case and despite good visualisation, the ETT cannot be directed through the vocal cords.

[0010] Poor visualisation of the vocal cords during direct laryngoscopy often means that there is a more sharply angled pathway that the ETT must follow in

the oropharynx. This sharp angle of approach can make it impossible to direct an ETT through the vocal cords without using a specialised introducer.

[0011] When a VLS is used to improve a poor view of the vocal cords obtained with direct laryngoscopy, it is expected that the ETT must follow a very sharply angled pathway in the oropharynx. It is generally considered essential to use an introducer to negotiate this sharp angle. This is one of the limitations of the VLS (i.e., it gives a good view of the vocal cords, but makes it more difficult to pass the ETT).

[0012] Specialized introducers are designed to guide the ETT through the vocal cords. The introducers can be bent to fit the shape of the pathway required for intubation, thus increasing the chance of successful ETT placement. There are two main types of introducer: (a) stylet or (b) bougie. The stylet is placed within the lumen of the ETT before intubation and is used as a shaper or stiffener of the ETT. It functions as a single unit combined with the ETT during intubation and is then removed after the tip of the ETT enters the vocal cords. The bougie is used as a primary device which is passed through the vocal cords into the trachea. The ETT is then slid (railroaded) over the bougie to enter the trachea and the bougie is then removed through the ETT lumen. It functions as a conduit for the ETT and is more versatile than a stylet. It is a very important piece of equipment used to direct the ETT through the vocal cords during a difficult intubation.

[0013] The introducers have limitations and they can fail. Referring to Figs. 2 and 3, when an introducer has to follow a very sharp angle of approach in the oropharynx, it can be very difficult to direct the tip through the vocal cords. The introducer can be bent into the shape of this sharp approach angle, however two force vectors need to be considered in determining successful placement. Force is applied along the longitudinal vector of the shaft of the introducer which needs to be transmitted to a vector plane aligned with the tip towards the vocal cords so it can advance. There is a certain oropharyngeal approach angle beyond which the force applied along the longitudinal vector will be unable to advance the tip in

its required vector (i.e., pushing the introducer from the shaft will not advance a sharply bent distal tip through the vocal cords).

[0014] If an introducer is successfully directed through the vocal cords after following a sharp angle of approach, it can then become stuck against the anterior wall of the trachea immediately below the vocal cords. The lumen of the trachea follows another acute angle away from the approach direction of the introducer at the vocal cords. This can make it very difficult to direct the introducer or ETT into the trachea despite passing through the vocal cords. (See Fig. 5.) This can also result in a failed intubation. Some of the commonly used bougies have an anteriorly angulated “coude” tip (which is recommended) however this can increase the chance of becoming stuck against the anterior tracheal wall as described above when there is a sharp approach angle.

[0015] The more difficult it is to visualise the vocal cords and the sharper the approach angle to the vocal cords means it is more difficult to successfully use an introducer. The VLS is particularly susceptible to this type of failure in a difficult intubation scenario due to its non-“line of sight” view. A well recognised and commonly reported cause of difficult or failed intubation when using a VLS involves failure to direct the ETT or introducer into the vocal cords despite good visualisation. (See Fig. 4.)

[0016] Accordingly, there exists a need to provide an improved device less prone to problems such as those described above. The present invention seeks to lessen these problems by providing a device which allows the intubation of a patient without significant difficulties associated with conventional devices.

[0017] It will be clearly understood that, if a prior art publication is referred to herein, this reference does not constitute an admission that the publication forms part of the common general knowledge in the art in Australia or in any other country.

Summary

[0018] In one preferred aspect, the present invention is directed to a bougie with an adjustable distal tip. It preferably has a distal spring that facilitates movement of the distal tip. The movement is controlled by an internal wire connecting the spring to a proximal cap on the bougie. By pulling the cap off the bougie a short distance, a longitudinal force applied to the wire in a proximal direction bends the spring. This moves the bougie tip up to 90 degrees in an anterior plane. When the cap is released, the bougie tip (and spring) returns to its original neutral position by using the stored elastic energy of the spring.

[0019] It is preferably designed to handle like an existing bougie combined with a laryngoscope or VLS. The bougie tip can be flexed upwards and directed into the vocal cords when there is a sharp oropharyngeal approach angle (Figs. 10 and 11). The tip also has the ability to passively flex downwards when passing through the vocal cords to avoid catching on the anterior tracheal wall (Figs. 12 and 13). It therefore has two planes of movement which can assist passage through a difficult or sharply angled oropharynx. It also has the potential to reduce airway trauma due to the shock absorbing properties of the spring.

[0020] It is easy to use and will be easy to learn with many features of the existing bougies. It preferably retains all of the properties of a traditional bougie including the ability to railroad or exchange an ETT without removing the bougie from the trachea.

[0021] When there is a sharp approach angle in the oropharynx, the invention is initially inserted like a conventional bougie during laryngoscopy. The flexible shaft can be angled or bent to match the shape of the oropharyngeal passage and the tip directed towards the vocal cords by advancing the shaft in a distal direction. As the distal tip of the bougie approaches the vocal cords, the proximal cap is pulled proximally (approximately 1cm) by an assistant (e.g., nurse, technician, anaesthetist, surgeon or other critical care physician). This flexes the distal bougie tip in an anterior direction to line up with the vocal cords. Further

advancement of the shaft distally will allow the distal bougie tip to pass through the vocal cords into the trachea.

[0022] The present invention in one preferred aspect provides for a device for use with an endotracheal tube. The device includes a shaft having a proximal end, a distal end, a length from the proximal end to the distal end, a central longitudinal axis through the proximal and distal ends, and a wall from the distal end to the proximal end, the distal end including a tip. The wall forms a passage with a length from the distal end towards the proximal end, the wall including a flexible region proximate the tip. The wall outside of the flexible region both distally and proximally of the flexible region is of a stiffness greater than the flexible region, a majority of the length of the shaft being configured to fit within the endotracheal tube. The device further includes a cord or cords having distal and proximate ends, wherein the one or more distal ends are attached to an interior portion of the wall; and a handle operationally attached to the one or more of proximate ends for pulling the cord or cords to move the tip away from the central longitudinal axis of the shaft.

[0023] In another preferred aspect, the present invention provides for a device for use with an endotracheal tube. The device includes a shaft having a proximal end, a distal end, a length from the proximal end to the distal end, a passage, and a central longitudinal axis through the proximal and distal ends, the distal end including a tip and a spring proximate the tip, the spring having a leading end oriented toward the tip, the spring having a trailing end oriented toward the proximal end. The leading end of the spring is spaced from the distal-most portion of the tip by at least a distance greater than the maximum inner diameter of the spring, a majority of the length of the shaft being configured to fit within the endotracheal tube. The device further includes a cord having one end attached to the passage; and a handle operationally attached to another end of the cord for pulling the cord distally to move the tip away from the central longitudinal axis of the shaft, the cord extending along a majority of the length of the passage.

[0024] In a further preferred aspect, the present invention provides a method for introducing an endotracheal tube through the vocal cords and into the trachea of a patient, the trachea having an entrance and a central longitudinal axis. The method includes advancing a portion of a distal end of a bougie towards the vocal cords of the patient, the distal end including a tip and a flexible region; retracting a portion of the flexible region which moves the distal tip in an anterior or upwards direction further towards the vocal cords (as visualised during laryngoscopy or videolaryngoscopy) until the tip is in a direction generally parallel to the central longitudinal axis of the trachea; advancing the distal end of the bougie into the trachea after the tip is generally parallel to the central longitudinal axis of the trachea; and maintaining the bougie in place while guiding an endotracheal tube over the bougie to insert the endotracheal tube into the patient.

[0025] In an additional preferred aspect, the present invention provides a method for introducing an endotracheal tube through the vocal cords and into the trachea of a patient. The method includes advancing a portion of a distal end of a bougie towards the vocal cords of the patient, the distal end including a tip and a flexible region; retracting, with a single hand, a portion of the flexible region in a first direction which moves anteriorly and upwards further towards the vocal cords while directing the tip in a second direction generally opposite to the first direction (e.g., posteriorly and downwards in the plane of the longitudinal axis of the trachea); advancing, with the single hand, the distal end of the bougie into the trachea after the tip is generally in the second direction; and maintaining the bougie in place while guiding an endotracheal tube over the bougie to insert the endotracheal tube into the patient.

[0026] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. In the present specification and claims, the word “comprising” and its derivatives including “comprises” and “comprise” include each of the stated integers, but does not exclude the inclusion of one or more further integers. As used herein, “proximal” is illustrative of a portion closer

to an intended user, from the user's perspective, while "distal" is illustrative of a portion away from the intended user.

[0027] The claims as filed and attached with this specification are hereby incorporated by reference into the text of the present description.

[0028] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Brief Description of the Figures

[0029] Fig. 1 is a partial cross-sectional side view of a conventional bougie being used with a standard laryngoscope.

[0030] Fig. 2 is a partial cross-sectional side view of an attempt to direct a tip of a conventional bougie through the vocal cords using a standard laryngoscope.

[0031] Fig. 3 is a partial cross-sectional side view of the further progression of the attempt of Fig. 2.

[0032] Fig. 4 is a partial cross-sectional side view of a conventional bougie being used with a videolaryngoscope resulting in a failed intubation.

[0033] Fig. 4A is a partial front elevation view of the tip of the bougie of Fig. 4 showing the image that would be viewed on the videolaryngoscope screen.

[0034] Fig. 5 is a partial cross-sectional side view of a conventional bougie with a coude tip stuck against the anterior wall of the trachea after passing through the vocal cords.

[0035] Fig. 6 is a partial cross-sectional side view of a bougie in accordance with a preferred embodiment of the present invention.

[0036] Fig. 7 is a partial top plan view of the bougie of Fig. 6.

[0037] Fig. 8 is a partial cross-sectional side view of the bougie of Fig. 6 in a flexed position.

[0038] Fig. 9 is a partial top plan view of the bougie of Fig. 6 in a flexed position with an "S" shape.

[0039] Fig. 10 is a partial cross-sectional side view of the bougie of Fig. 6 being inserted into a patient in accordance with a preferred method of the present invention.

[0040] Fig. 11 is a partial cross-sectional side view of the tip of the bougie of Fig. 6 entering the trachea in accordance with the method of Fig. 10, when used with a videolaryngoscope.

[0041] Fig. 11A is a partial front elevation view of the tip of the bougie of Fig. 6 used in Fig. 11 showing the image that would be viewed on the videolaryngoscope screen.

[0042] Fig. 12 is a partial cross-sectional side view of the tip of the bougie of Fig. 6 sliding down the trachea in accordance with the method of Fig. 10.

[0043] Fig. 13 is a partial cross-sectional side view of the tip and shaft of the bougie of Fig. 6 inserted in the trachea in accordance with the method of Fig. 10.

[0044] Fig. 14 is a partial cross-sectional side view of a bougie in accordance with another preferred embodiment of the present invention.

[0045] Fig. 15 is a partial cross-sectional side view of the bougie of Fig. 14 in a flexed position.

Detailed Description of the Drawings

[0046] Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings.

[0047] Figs. 6-13 show a preferred embodiment of a bougie 100 having a shaft 102 with a spring 104, a cap 106 at one end thereof, and a cord 108 connected to cap 106 for moving a distal portion of the bougie. In use, a user pulls cap 106 proximally to retract cord 108, which is preferably attached to a portion of the interior of spring 104. Movement of the distal portion of the bougie preferably occurs in two directions, the first and primary movement being active, and the secondary movement being passive and generally in a direction opposite to that of the primary movement. Active movement of a portion of spring 104 anteriorly moves the distal bougie tip in the same primary direction towards the vocal cords. Passive movement of the distal part of spring 104 allows the distal tip of shaft 102 to then move in a secondary direction, opposite to that of the first primary active movement. This secondary passive movement brings the distal bougie tip in line with the longitudinal axis of the trachea and enhances control and insertion of the bougie into difficult passages such as the trachea, especially when a sharp or acute oropharyngeal approach angle occurs (i.e., with a VLS used for a difficult airway). The preferred elements of bougie 100 and their interrelationship are described below.

[0048] Referring to Figs. 6-9, bougie 100 includes shaft 102 having a proximal end 110, a distal end 112, and a wall 114 from proximal end 110 to distal end 112. Wall 114 preferably forms a passage 116 having a length from distal end 112 towards proximal end 110. Distal end 112 preferably includes a tip 118 configured for entry into an airway of a patient. Wall 114 includes a preferably resiliently flexible region, preferably in the form of spring 104, proximate tip 118.

[0049] As shown in Figs. 6 and 7, spring 104 has a leading or distal end 120, a trailing or proximal end 122, and an interior portion 124 which preferably forms a portion of the interior of passage 116. Preferably, leading end 120 of spring 104 is spaced from the distal-most portion of tip 118, more preferably by at least a distance greater than the maximum inner diameter of spring 104. Spacing the spring from the distal point of the tip advantageously enhances the ability of bougie 100 to move in more than one direction when used to navigate through difficult passages, as will be described in further detail below. Referring again to

Fig. 6, preferably a portion of wall 114 outside of spring 104, both distally and proximally of spring 104, is of a stiffness greater than that of spring 104.

Preferably, the portion of the wall outside of spring 104, both distally and proximally of spring 104, is made of the same material.

[0050] Referring to Figs. 6 and 7, bougie 100 preferably includes a retracting means to move the distal portion of the bougie. Preferably, the retracting means includes cord 108 connected to cap 106 at one end thereof, and connected to spring 104 at another end thereof. It will be appreciated that other retracting means may be used, such as spring mechanisms, and that the cord embodiment described below is exemplary only. Continuing with reference to Figs. 6 and 7, cord 108 includes a proximal end 126 connected to cap 106, and a distal end preferably attached to a portion of passage 116. More preferably, the distal end of cord 108 is attached to interior portion 124 of spring 104. As shown in Fig. 7, the distal end of cord 108 is preferably attached to interior portion 124 at more than one location, more preferably, at least two locations. Thus, the distal end of cord 108 preferably includes a first distal wire 128 and a second distal wire 130 for attachment to two different, spaced-apart first and second attachment points 132, 134, respectively, within passage 116. Attachment points 132, 134 are preferably spaced-apart from one another in the range of 90 to 180 degrees relative to the central longitudinal axis of the shaft. It will be appreciated that two wires may be used to connect to cap 106, run internally through substantially the entire length of the shaft 102, pass through guide 136 and then branch to connect to the attachment points 132 and 134.) First attachment point 132 and second attachment point 134 are preferably located proximal of leading end 120 of spring 104, more preferably in a distal half of spring 104, and most preferably, closer to leading end 120 than trailing end 122 of spring 104. First distal wire 128 and second distal wire 130 preferably pass through a guide 136 and are connected to cap 106. Guide 136 is preferably attached to a portion of passage 116. Positioning the attachment points of the cord proximally of the leading end of the spring advantageously enhances the ability of bougie 100 to move in more than

one direction when used to navigate through difficult passages, as will be described in further detail below.

[0051] Referring to Figs. 6-9, cap 106 is preferably configured for gripping by a user to retract or pull cord 108 to move the distal portion of bougie 100. Cap 106 may be shaped in a variety of ways in order to suit the needs of the user. It will be appreciated that a retraction mechanism other than a cord and cap may be used to move the distal portion of the bougie. For example only, the proximal portion of the bougie may include a retractable, spring-loaded handle so that the user may squeeze a trigger to move the distal portion of bougie 100.

[0052] As shown in Figs. 6 and 7, bougie 100 preferably includes a sleeve 138 of a thin, pliable medical grade plastic coating to externally cover spring 104 and a portion of the wall of shaft 102 on either side of spring 104.

[0053] Preferred dimensions are set forth below, although it will be appreciated that the dimensions may be varied as suitable for the intended application. Shaft 102 is preferably in the range of 60-80 cm, more preferably 70 cm in length. Shaft 102 preferably has an outer diameter in the range of 4.0 to 5.0 mm, more preferably 4.5 mm. Tip 118 preferably has a length in the range of 20-30 mm, while cap 106 preferably has a length in the range of 10-20 mm. It will be appreciated that the dimensions above may be modified for use in paediatric applications as desired.

[0054] Spring 104 preferably has a length along its central longitudinal axis in the range of 20-40 mm, with a preferred outer diameter of 4.6-4.8 mm. Preferably the outer diameter of spring 104 is equal to the outer diameter of shaft 102 so that the bougie has a uniform dimension throughout its length.

[0055] Sleeve 138 preferably has a length sufficient to cover spring 104 and a portion of the wall on either side of the spring. For example, sleeve 138 preferably has a length in the range of 30-60 mm. It will be appreciated that sleeve 138 may be modified to extend the entire length of the bougie if desired.

[0056] First wire 128 and second wire 130 preferably each have a diameter of approximately 0.3 mm. First attachment point 132 and second attachment point 134 each are preferably located approximately 5-10 mm from leading end 120 of spring 104. The attachments of first wire 128 and second wire 130 from 5-10 mm from the leading end of spring 104 allow tip 118 to move in a secondary plane opposite to that caused by the wire tension. This allows the tip of bougie 100 to be actively moved in an anterior/dorsal plane by the wire, but then move passively posteriorly as it contacts with the anterior wall of the trachea (described in further detail below). This results in a "S" shape as shown in Fig. 9, and preferably prevents the distal tip from becoming stuck against the anterior wall of the trachea as it passes through the vocal cords at a sharp approach angle. It will be appreciated that these dimensions are representative only and may be varied as appropriate. Additionally, the ranges described above may include a subset of ranges therein without departing from the scope of the present invention.

[0057] Having described the preferred components of bougie 100, a preferred method of use will now be described with reference to Figs. 10-13. Referring to Figs. 10 and 11, an anaesthetist inserts a standard laryngoscope (Fig. 10) or preferably a videolaryngoscope (Fig. 11) into the patient. The initial position of bougie 100 is preferably in a neutral position with cap 106 sitting at the end of shaft 102. In the initial position, there is preferably no tension on the cord, and the spring and distal tip are in straight alignment with the rest of the shaft. Thereafter, the anaesthetist inserts bougie 100 into the patient, preferably through an airway passage such as the mouth. Once the distal portion of bougie 100 has entered the patient, a portion of the distal end of bougie 100 is advanced towards the vocal cords of the patient as shown in Figs. 10 and 11. In order to facilitate the procedure, an image 140 (Fig. 11A) of the upper airway may preferably be obtained using video laryngeal scope 12. Preferably, the image is obtained proximate the tip while the distal portion of the bougie is within the patient.

[0058] The image obtained from the imaging device proximate the tip (such as video laryngeal scope 12) may be viewed on a separate screen connected to the

device by a wired or wireless mechanism. The imaging screen may include a smart phone and utilize a smart phone application.

[0059] Continuing with reference to Fig. 11, a portion of spring 104 is retracted, preferably by pulling cap 106. The pulling of cap 106 results in a primary movement of the distal spring/flexible tip away from the central longitudinal axis of the bougie shaft and towards the vocal cords and into the trachea. This actively moves the bougie tip in a primary direction, anteriorly, up and towards the vocal cords.

[0060] Referring to Fig. 12, after the bougie tip passes through the vocal cords into the trachea, tip 118 passively moves in a secondary direction, posteriorly, down and away from the vocal cords to lie in a direction generally parallel to the central longitudinal axis of the trachea. Preferably, the spring portion is retracted when the anaesthetist or their assistant pulls on cord 108 using cap 106 attached at the end of the cord. The longitudinal tension on cord 108 caused by the pulling on the cap is transmitted to spring 104, which shortens on its dorsal surface. This causes the spring and the distal tip of the bougie to bend in a dorsal direction up to 90 degrees. The attachments of first distal wire 128 and second distal wire 130 proximal of the leading end of the spring and within the spring facilitate movement of the distal tip of the bougie in a secondary plane opposite to that caused by the wire tension. This permits tip 118 to be actively moved in an anterior/dorsal plane by cord 108, but then move passively posteriorly as it contacts with the anterior wall of the trachea. This results in a "S" shape and helps to prevent the distal tip from becoming stuck against the anterior wall of the trachea as it passes through the vocal cords, especially if this passage through the vocal cords occurs at a sharp angle.

[0061] Referring to Fig. 13, when cap 106 is released, the longitudinal tension on the wire will be released and spring 104 will return to its original neutral position using the elastic energy gained when bent (compressed on the dorsal side). This passive recoil of the spring returns distal tip 118 to its neutral position and cap 106 moves back to sit on the proximal part of shaft 102 of bougie 100.

Distal end 112 of bougie 100 is advanced into the trachea after tip 118 is generally parallel to the central longitudinal axis of the trachea. Thereafter, bougie 100 is maintained in place while an endotracheal tube is guided over the bougie to insert the endotracheal tube into the patient. The bougie is then removed from within the ETT by pulling it out proximally and the ETT preferably remains in place to be used for ventilation of the patient.

[0062] Preferably, the primary procedure is conducted by the anaesthetist without the need of an assistant. For example, after the tip of the bougie has been advanced towards the vocal cords, the anaesthetist, using a single hand, retracts a portion of the spring to actively move the bougie tip in its primary direction anteriorly, up and towards the vocal cords. Once the bougie tip is guided through the vocal cords into the trachea, the distal spring and bougie tip may passively move in its secondary direction, posteriorly, down and away from the vocal cords to lie in a direction parallel with the central longitudinal axis of the trachea. Thereafter, the distal end of the bougie is advanced, using the single hand, deeper into the trachea after the tip is generally in the second direction. Alternatively, it is equally feasible to use the assistant that is normally required for use of the traditional bougie during intubation and railroading of the ETT.

[0063] It will be appreciated that the steps described above may be performed in a different order, varied, or some steps added or omitted entirely without departing from the scope of the present invention. For example, an airway introducer incorporating a flexible region in the form of a spring such as described above may be used for other procedures, and used through other passages where internal navigation is difficult. Examples include navigation of airway passages such as the nasal passage, other procedures such as a colonoscopy, and/or procedures where artificial insertions are made (e.g., laparoscopic procedures), and a tip of a surgical instrument is required to be configured to navigate around difficult areas.

[0064] Figs. 14 and 15 show another embodiment of a bougie 200, which is similar to bougie 100 except that bougie 200 includes an internal lumen 242 sized

and configured for pull wire 208 to pass therethrough along a substantial portion of the length of bougie 200. Wire 208 is attached distally of distal end 212 at a single attachment point 244. Another difference is that the flexible region is formed as a series of corrugations at distal end 212. The corrugations are preferably integrally formed of the same material from a single mold, but vary in thickness. The flexible region may also be formed by the same material of the shaft, but comprising a lesser durometer. The operation of bougie 200 is similar to that of bougie 100 described above.

[0065] The foregoing description is by way of example only, and may be varied considerably without departing from the scope of the present invention. For example only, the shape of the tip may be varied as a blunt tip and/or a straight or coude tip or reverse coude tip. The flexible region may be configured as a spring as set forth above, or may be a flexible, unitary structure having a series of corrugations. Where the flexible region is corrugated, it may be made from the same material as the remainder of the shaft. If desired, where a spring is utilised, it may be made from the same material as the shaft, and may be formed from a non-metallic material, such as a medical grade plastic having sufficient resilience and stiffness qualities to function in a spring-like manner.

[0066] The flexible region may be manufactured without a spring if desired. For example only, the shaft may be formed with multiple layers, each layer being of differing length and flexibility or stiffness. As one example, the flexible region may be formed with a soft inner plastic layer and a harder outer coating layer (e.g., "jacket"). The softer, inner layer may have a length longer than that of the harder outer layer. The stiffer outer sheath layer provides rigidity for the main shaft to be held, shaped and directed, and the inner softer layer that preferably protrudes can be flexed, steered or directed by a guidance system such as a wire, which facilitates navigation through an angled airway pathway. As another example, the distal flexible region may not have a separate distal tip composed of a different material to that of the flexible region. The material forming the distal flexible segment, whether this be a spring or other flexible material, may extend all the way to and terminate at the distal tip of the bougie.

[0067] When using multiple layers, each layer may include one or more features to promote different degrees of stiffness. For example, in addition to, or in place of different lengths, each layer may have a different thickness, include an embedded supporting structure, such as wire braiding or monofilament (with different wire configurations such as single, double or ribbon), and/or be made from a different material relative to another layer. Each layer may be manufactured with a variable stiffness along its length. A few benefits of encapsulating a wire braiding in a layer include better torque control and the ability to form a softer distal portion into a variety of curves, and kink resistance.

[0068] The shaft may include multiple lumens if desired. For example, the shaft may form a single, main lumen, with one or more smaller lumens extending along the interior of the shaft. Any interior lumens may be of differing diameter, shape and length relative to each other and/or to the length of the shaft. One or more of the lumens may be configured for a navigation control, such as a wire or guide wire to assist in directing the tip of the bougie. Instead of, or in addition to using a wire or guide wire, the navigation control may utilise a smaller diameter stiff tube with a highly lubricated outer coating (e.g., Teflon) located within a smaller dorsal lumen within the bougie. The stiff internal tube functions like a wire and is preferably attached to the distal tip (at a variable distance from the distal tip similar to that described above for the spring). The stiff internal tube is preferably configured to travel through the dorsal lumen to the proximal end of the bougie, where it is preferably configured to protrude and be grasped or pulled proximally. It will be appreciated that the proximal end of the stiff internal tube may be configured in a variety of ways for engagement by a user to move the internal tube. It will be further appreciated that the stiff internal tube may be solid if desired. The distal end of the internal tube may be curved or shaped to engage a similarly shaped portion of an internal lumen for better navigation if desired.

[0069] The retraction mechanism preferably includes a cord. Preferably the cord is formed from metallic wire. The cord may be formed from other materials such as a textile or plastic if desired. It will be appreciated from the above that an internal tube can be used instead of a cord and the use of the term cord

incorporates any longitudinal member that is able to transmit pulling force or tension applied to one end of the member to its other end. Where a plurality of wires are provided, a guide may be included proximally of the flexible region (such as shown in Fig. 6). Grooves may be included in the interior surface of the passage to facilitate guiding one or more the wires during movement of the tip. Preferably, no portion of the wire travels outside of the interior of the shaft while the shaft is in the patient. Travel of a wire outside the shaft while it is in the patient increases the risk of damage to delicate tissue structures.

[0070] The bougie may be modified with a variety of retraction mechanisms. The retraction mechanism may utilise a spring, or other “spring-like” mechanisms as desired, which may be configured for engagement with a trigger mechanism. For example only, a retractable pen-type mechanism may be utilised, similar to a retractable click pen mechanism utilizing a modified cam and spring mechanism. Attached to the proximal shaft of the bougie is a button that can be clicked. The button is attached to a cam mechanism that moves when the button is clicked up and down. An internal wire attached to the distal bougie tip (with its distal flexible spring mechanism) is attached to the proximal button “click-cam” mechanism. A second spring is coupled to the “click-cam” mechanism in a location within the bougie shaft proximate to the distal spring used for moving the bougie tip. This second spring is preferably used as a tensioning device attached to the wire to facilitate retraction when the proximal button is clicked in or out. The neutral position of the button may be the opposite to that of the click pen (i.e., button depressed down in the “pen open” position is neutral, and the button clicked up in the “pen closed” position facilitates the active retraction of the wire which moves the distal tip).

[0071] Another retraction mechanism may include a shaft bending mechanism. For example, bending part of the shaft proximate to the distal spring mechanism retracts an internal wire connected to the distal bougie tip. The internal wire is connected to the internal shaft of the bougie at a point proximate to the shaft bending point. The shaft bending point may include a second spring or a corrugated section, or include a section of bougie more flexible than the rest

of the shaft. Bending of the shaft results in retraction of the internal wire that is connected to the distal flexible mechanism and results in movement of the bougie tip away from the central longitudinal axis of the bougie.

[0072] A further exemplary retraction mechanism may include a shaft sliding mechanism. For example, a slide mechanism is located in the shaft of the bougie proximate to the distal spring mechanism. The internal wire attached to the distal spring mechanism is connected proximally to the slide mechanism on its internal surface. The slide is located on the exterior of the bougie shaft and can be slid proximally to retract the internal wire and result in movement of the distal bougie tip in a similar manner to the shaft bending mechanism described above.

[0073] Another example of a retraction mechanism includes use of an external wire mechanism. For example, the internal wire attached distally to the flexible spring mechanism exits the shaft of the bougie to become external to the bougie shaft at a point proximate to the distal 20cm to 30cm of the shaft. The external position of the wire can then be pulled directly to cause retraction of the internal wire and facilitate movement of the distal bougie tip. The proximal part of the external wire is preferably attached to the exterior of the bougie shaft proximate to its exit point.

[0074] The mechanism of controlling movement of the distal flexible region may involve an automated process. This automation may involve the use of a micromotor or micromotion system configured to fit within the internal shaft of the device (for example a longitudinal squiggle or vibration motor) coupled to an internal wire that produces torque and movement of the distal tip. This motorised mechanism may be powered by DC batteries (for example SR416SW batteries) or an external power source (e.g., USB). The automated mechanism may be coupled to an optical imaging device and controlled by an external mechanism utilizing the imaging screen of the optical device in a wired or wireless mechanism. This mechanism may include using a smart phone which may utilize a smart phone application.

[0075] The cap may be replaced with a trigger such as described above. It will be appreciated that the cap may be formed in a variety of ways to enable an anaesthetist to move the distal portion of the bougie.

[0076] The features described with respect to one embodiment may be applied to other embodiments, or combined with or interchanged with the features of other embodiments, as appropriate, without departing from the scope of the present invention.

[0077] The present invention in a preferred form provides an advantage of enhanced tip navigation with multi-directional movement, which lends itself to use in airway intubation or other medical or surgical procedures where difficult passages must be traversed. Another advantage is its ease of use. For example, a single person may use the instrument in one embodiment, or in another embodiment it is an easy manoeuvre for an assistant or second person to pull the cap. Conventional navigation instruments often require more than one person and it is usual to have an assistant when using a traditional bougie for a difficult intubation to railroad the ETT over the bougie.

[0078] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A device for use with an endotracheal tube, said device comprising:

a shaft having a proximal end, a distal end, a length from said proximal end to said distal end, a central longitudinal axis through said proximal and distal ends, and a wall from said distal end to said proximal end, said distal end including a tip, said wall forming a passage with a length from said distal end towards said proximal end, said wall including a flexible region proximate said tip, said wall outside of said flexible region both distally and proximally of said flexible region being of a stiffness greater than said flexible region, a majority of the length of said shaft being configured to fit within the endotracheal tube;

a cord or cords having distal and proximate ends, wherein the one or more distal ends are attached to an interior portion of said wall; and

a handle operationally attached to the one or more proximate ends of said cord or cords for pulling said cord or cords to move said tip away from the central longitudinal axis of said shaft.
2. The device of claim 1, wherein said flexible region is resiliently flexible.
3. The device of claim 1 or 2, wherein said flexible region comprises a spring.
4. The device of claim 1 or 2, wherein said flexible region comprises a series of corrugations.
5. The device of claim 1 or 2 wherein said flexible region has multiple layers comprising a soft inner plastic layer and a harder outer coating layer.
6. The device of claim 5 wherein one or more of the layers incorporate an embedded supporting structure.
7. The device of any of claims 1 to 6, wherein said wall outside of said flexible region both distally and proximally of said flexible region is made of the same material.

8. The device of any of claims 1 to 7, wherein said cord or cords distal ends are attached to an interior portion of said flexible region.
9. The device of any of claims 1 to 8, wherein said flexible region has a distal end connecting to said tip, cord or cords distal ends being attached to said interior portion of said wall proximal of said distal end of said flexible region.
10. The device of any of claims 1 to 8, wherein said flexible region has a distal end connecting to said tip and a proximal end connecting to said wall outside of said flexible region, said cord or cords distal ends being attached to said interior portion of said wall closer to said distal end of said flexible region than said proximal end of said flexible region.
11. The device of any of claims 1 to 8, wherein said cord or cords distal ends are attached to said interior portion of said wall in a distal half of said flexible region.
12. The device of any of claims 1 to 8, wherein said cord or cords distal ends is attached to said interior portion of said wall in a proximal half of said flexible region.
13. The device of any of claims 1 to 12, wherein said cord or cords extend proximally within the said passage along a majority of the length of said passage.
14. The device of any of claims 1 to 13 wherein the said cord or cords extend internally through substantially the entire length of the said passage of the shaft.
15. The device of any of claims 1 to 14 wherein the handle is a spring loaded trigger operated handle.
16. The device of any of claims 1 to 14 where in the handle incorporates a cam and spring mechanism connected to a button that pulls on the cord or cords when the button is depressed.
17. The device of any claims 1 to 14 wherein the handle is incorporated into an extended shaft of the device, wherein the extended shaft has a shaft bending

mechanism incorporating a second flexible region at the proximate end of the extended shaft, wherein bending the second flexible region causes the cord or cords to be pulled.

18. The device of any of claims 1 to 14 wherein the handle comprises a slide mounted upon an exterior surface of the said wall of device proximate the flexible region, wherein the a portion of the slide is mounted internally within the passage of the device and wherein moving the slide proximally pulls the cord or cords.

19. The device of any of claims 1 to 14 wherein the handle comprises a mechanism that communicates with one or more motors contained within the passage of the said device wherein said one or more motors are coupled to and provide tension on the cord or cords when the mechanism is activated.

20. The device of claim 19 wherein the mechanism comprises a smartphone or portable computing device connected to the said one or more motors and wherein the smartphone or portable computing device is further adapted to display an image captured by optical sensors incorporated at the distal tip of the device.

21. The device of any of claims 1 to 20 in which the said distal tip of the shaft, in addition to actively moving away from the longitudinal axis of the shaft as a result of pulling the cord or cords, may also move passively in the opposite plane of motion in response to force applied to the said distal tip of the shaft.

22. The device of any of claims 1 to 21 wherein there is one cord.

23. The device of claim 22, wherein said distal end of said cord bifurcates into a plurality of ends which then attach to the said interior portion of said wall by way of a plurality of attachment points.

24. The device of any of claims 1 to 21 wherein there are two cords connected at their distal ends to the interior of said wall by way of two attachment points.

25. The device of any one of claims 23 or 24 wherein the attachment points are spaced-apart from one another in the range of 90 to 180 degrees relative to the central longitudinal axis.

26. A device for use with an endotracheal tube, said device comprising:

a shaft having a proximal end, a distal end, a length from said proximal end to said distal end, a passage, and a central longitudinal axis through said proximal and distal ends, said distal end including a tip and a spring proximate said tip, said spring having a leading end oriented toward said tip, said spring having a trailing end oriented toward said proximal end, said leading end of said spring being spaced from the distal-most portion of said tip by at least a distance greater than the maximum inner diameter of said spring, a majority of the length of said shaft being configured to fit within the endotracheal tube;

a cord having one end attached to said passage; and

a handle operationally attached to another end of said cord for pulling said cord to move said tip away from the central longitudinal axis of said shaft, said cord extending along a majority of the length of said passage.

27. The device of claim 26, wherein said shaft outside of said spring both distally and proximally of said spring is made of the same material.

28. The device of claims 26 or 27, wherein said cord is attached to an interior portion of said spring.

29. The device of any of claims 26 to 28, wherein said cord is attached at two attachment points in said passage.

30. The device of claim 29, wherein said attachment points are spaced-apart one another in the range of 90 to 180 degrees relative to the central longitudinal axis.

31. The device of any of claims 26 to 30, wherein said cord is attached to said passage proximal of said leading end of said spring.

32. The device of any of claims 26 to 30, wherein said cord is attached to said passage closer to said leading end of said spring than said trailing end of said spring.

33. The device of any of claims 26 to 30, wherein said cord is attached to said passage closer to said trailing end of said spring than said leading end of said spring.

34. The device of any of claims 26 to 30, wherein said cord is attached to said passage in a distal half of said spring.

35. A method for introducing an endotracheal tube through the vocal cords and into a trachea a patient, the trachea having an entrance and a central longitudinal axis, the method comprising:

advancing a portion of a distal end of a bougie towards the vocal cords of the patient, the distal end including a tip and a flexible region;

retracting a portion of the flexible region to actively move the bougie tip in a primary direction, anteriorly, up and towards the vocal cords;

guiding the bougie tip through the vocal cords to enter the proximal trachea while it remains in its actively retracted position;

returning the retracted portion of the flexible region to a neutral position while directing the tip in a direction generally parallel to the central longitudinal axis of the trachea by allowing the tip to passively move in a secondary direction, posteriorly, down and away from the vocal cords;

advancing the distal end of the bougie deeper into the trachea after the tip is generally parallel to the central longitudinal axis of the trachea; and

maintaining the bougie in place while guiding an endotracheal tube over the bougie to insert the endotracheal tube into the patient.

36. A method for introducing an endotracheal tube through the vocal cords and into a trachea of a patient, the method comprising:

advancing a portion of a distal end of a bougie towards the vocal cords of the patient, the distal end including a tip and a flexible region;

retracting, with a single hand, a portion of the flexible region to actively move the bougie tip in a primary direction, anteriorly, up and towards the vocal cords;

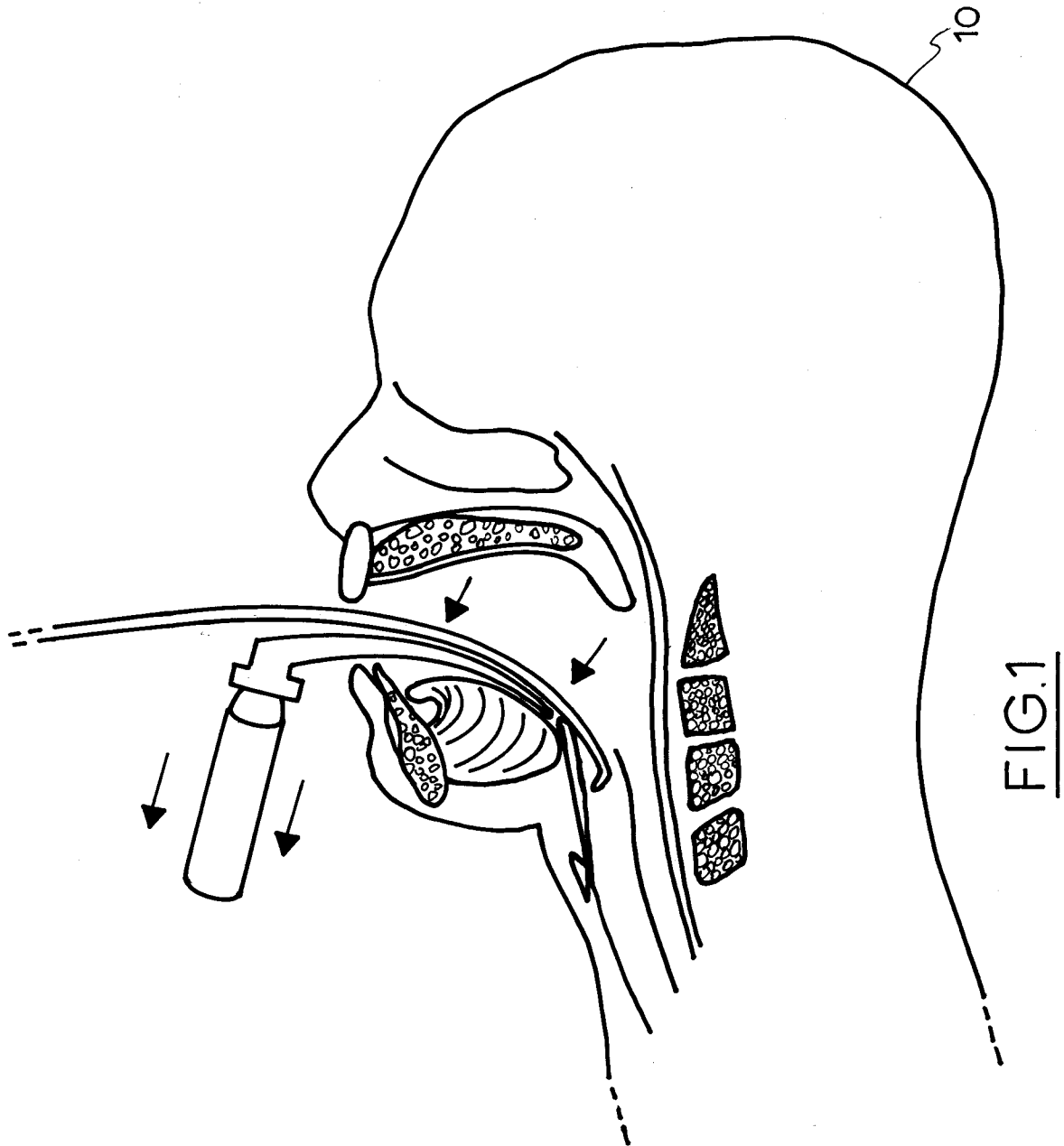
guiding, with the single hand, the bougie tip through the vocal cords to enter the proximal trachea while it remains in its actively retracted position;

returning, with the single hand, the retracted bougie tip back to a neutral position while directing the tip in a direction generally parallel to the central longitudinal axis of the trachea by allowing the tip to passively move in a secondary direction, posteriorly, down and away from the vocal cords;

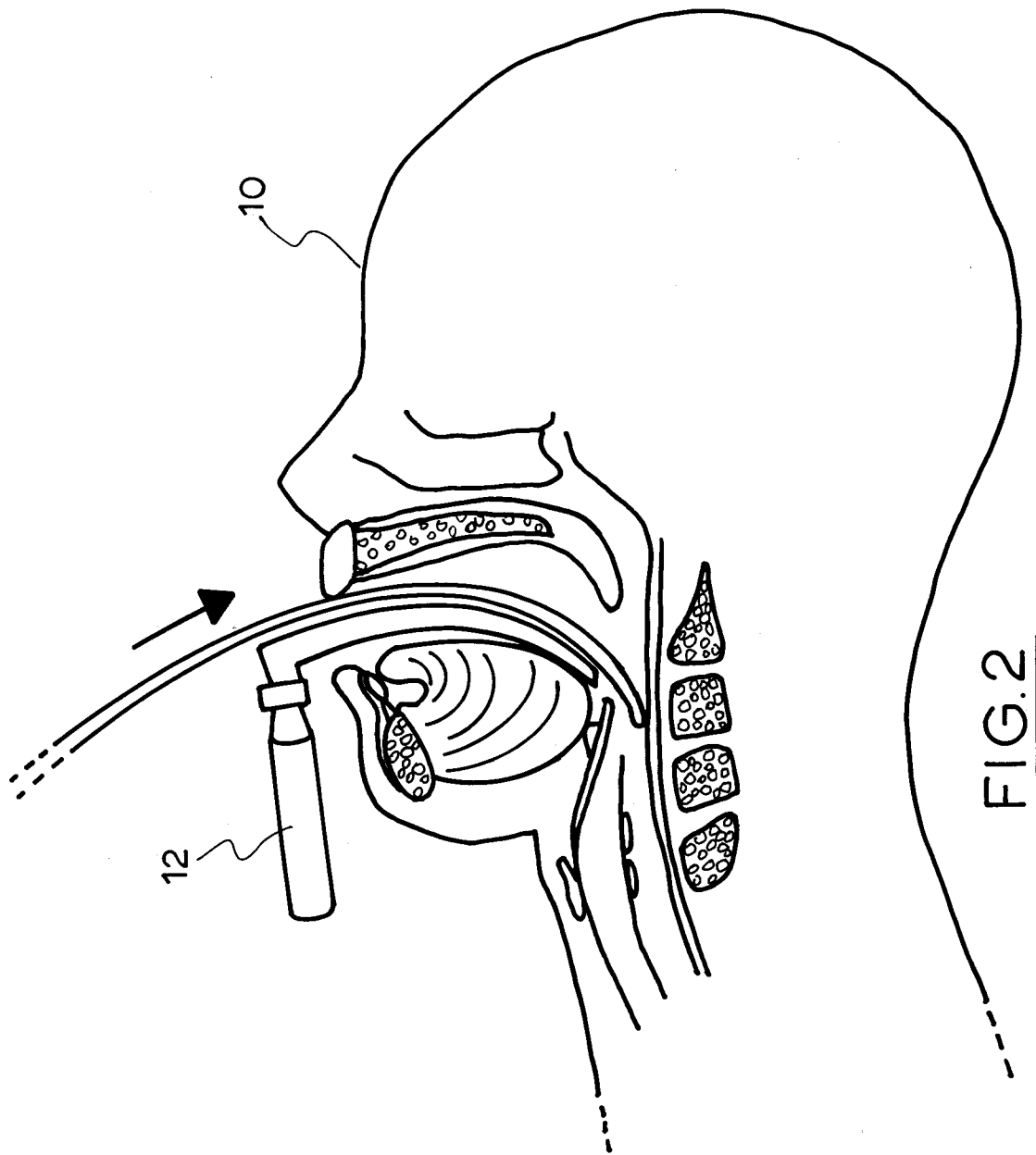
advancing, with the single hand, the distal end of the bougie deeper into the trachea after the tip is generally in the second direction; and

maintaining the bougie in place while guiding an endotracheal tube over the bougie to insert the endotracheal tube into the patient.

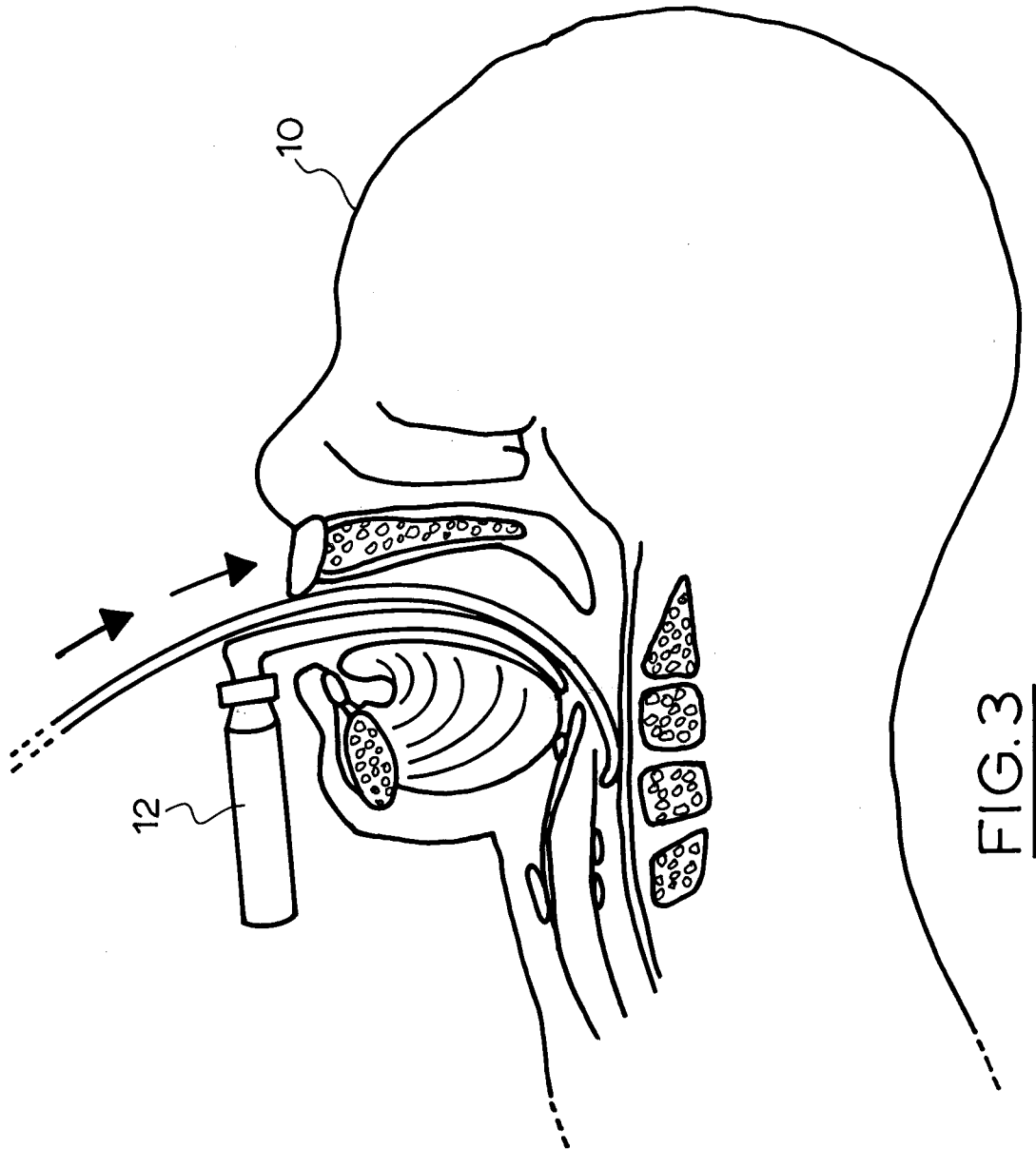
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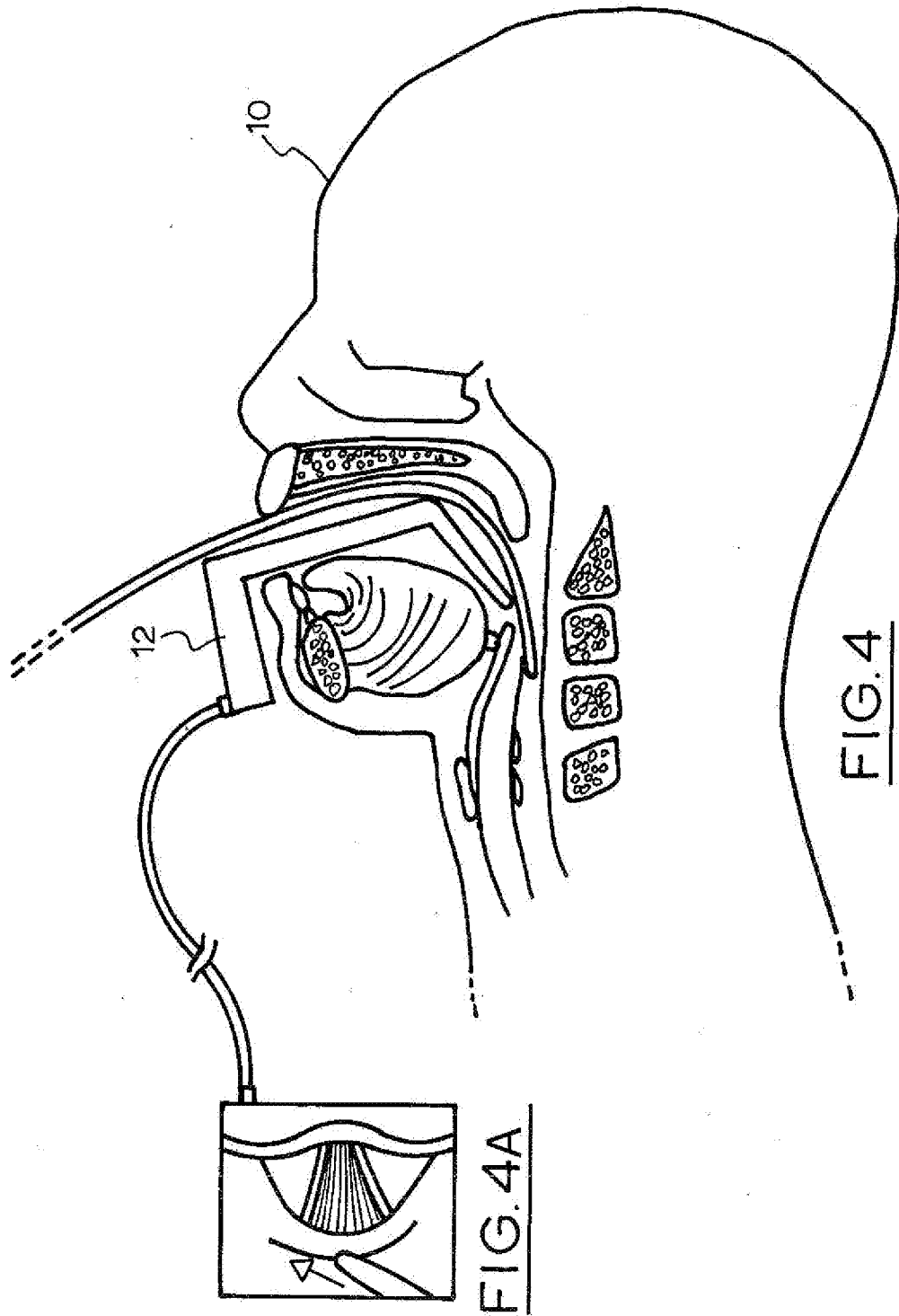


FIG. 4

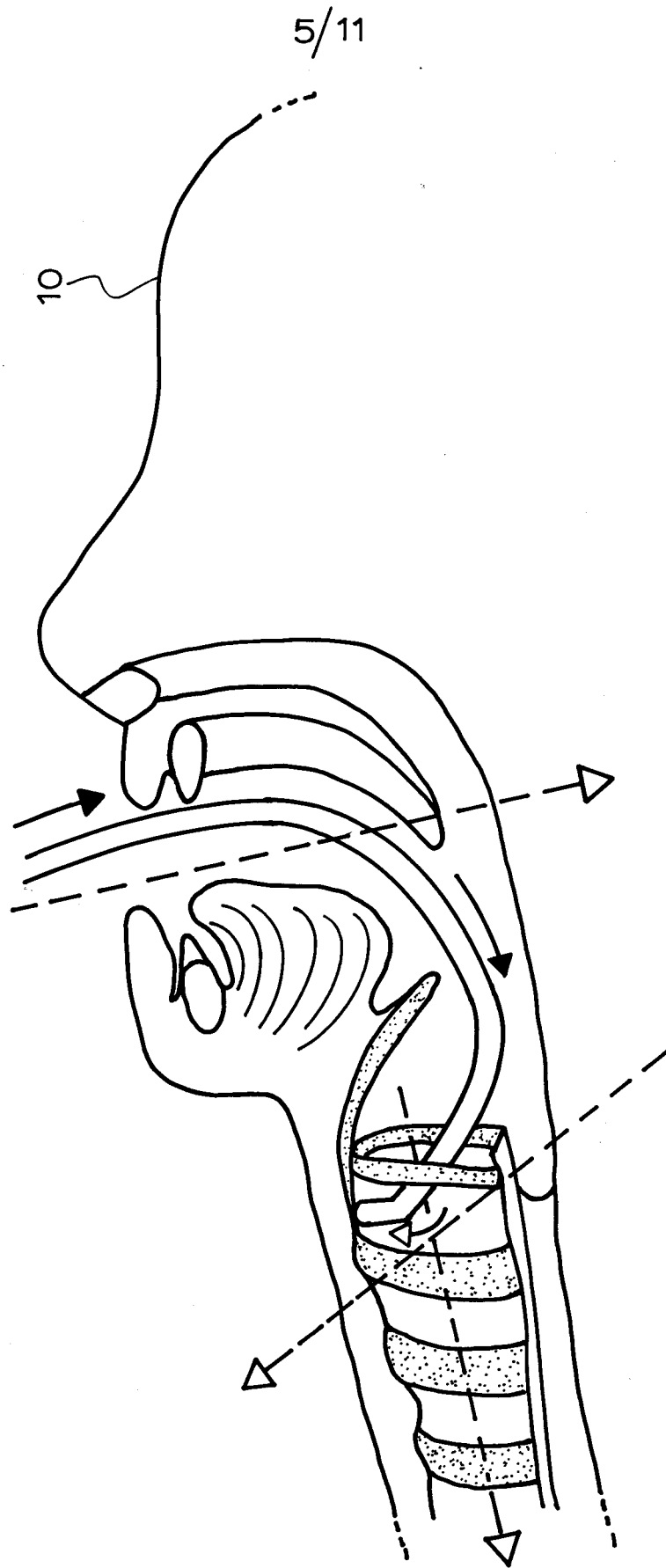
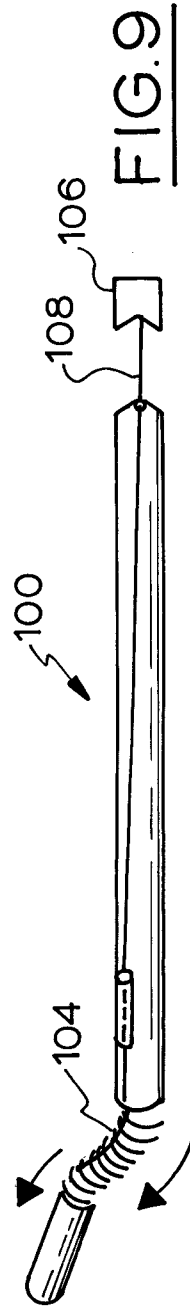
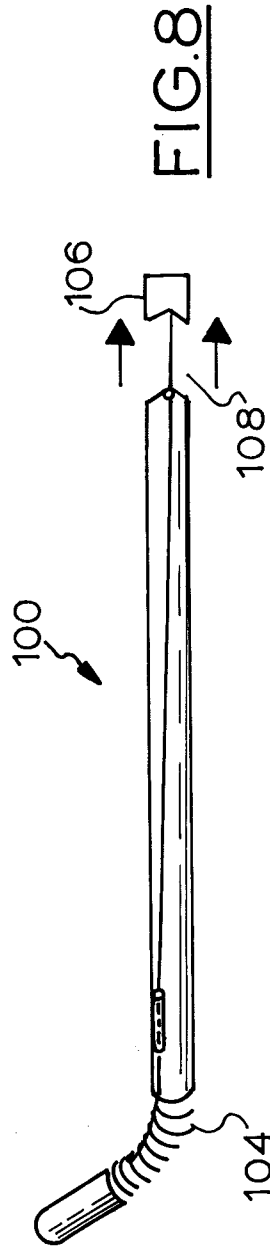
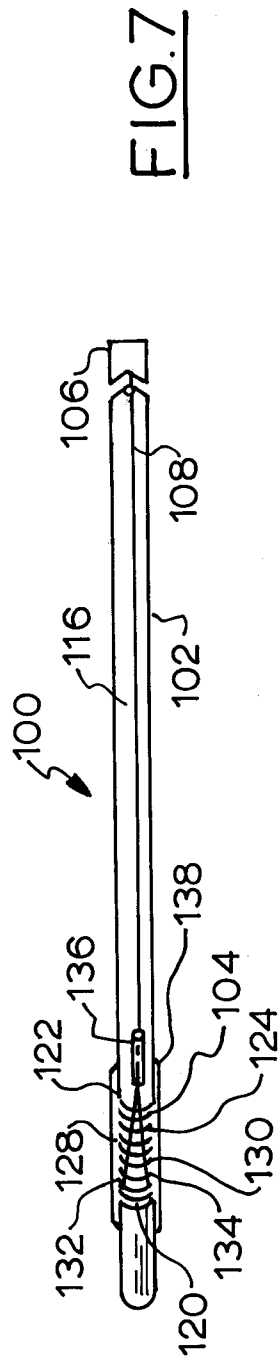
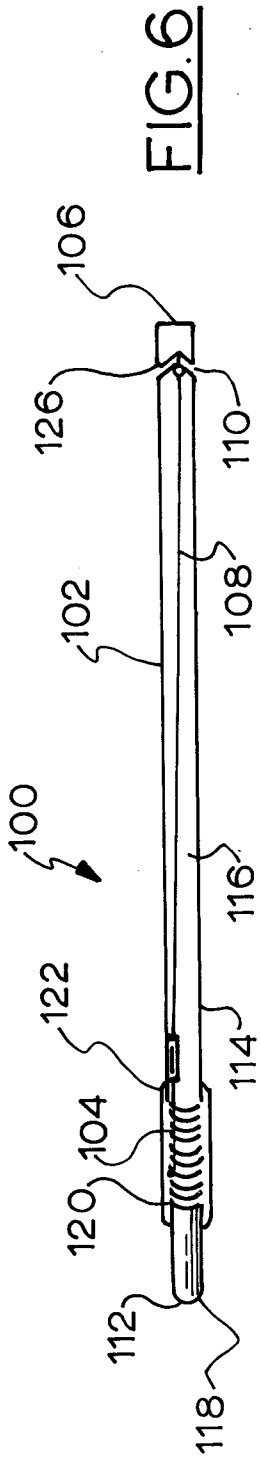
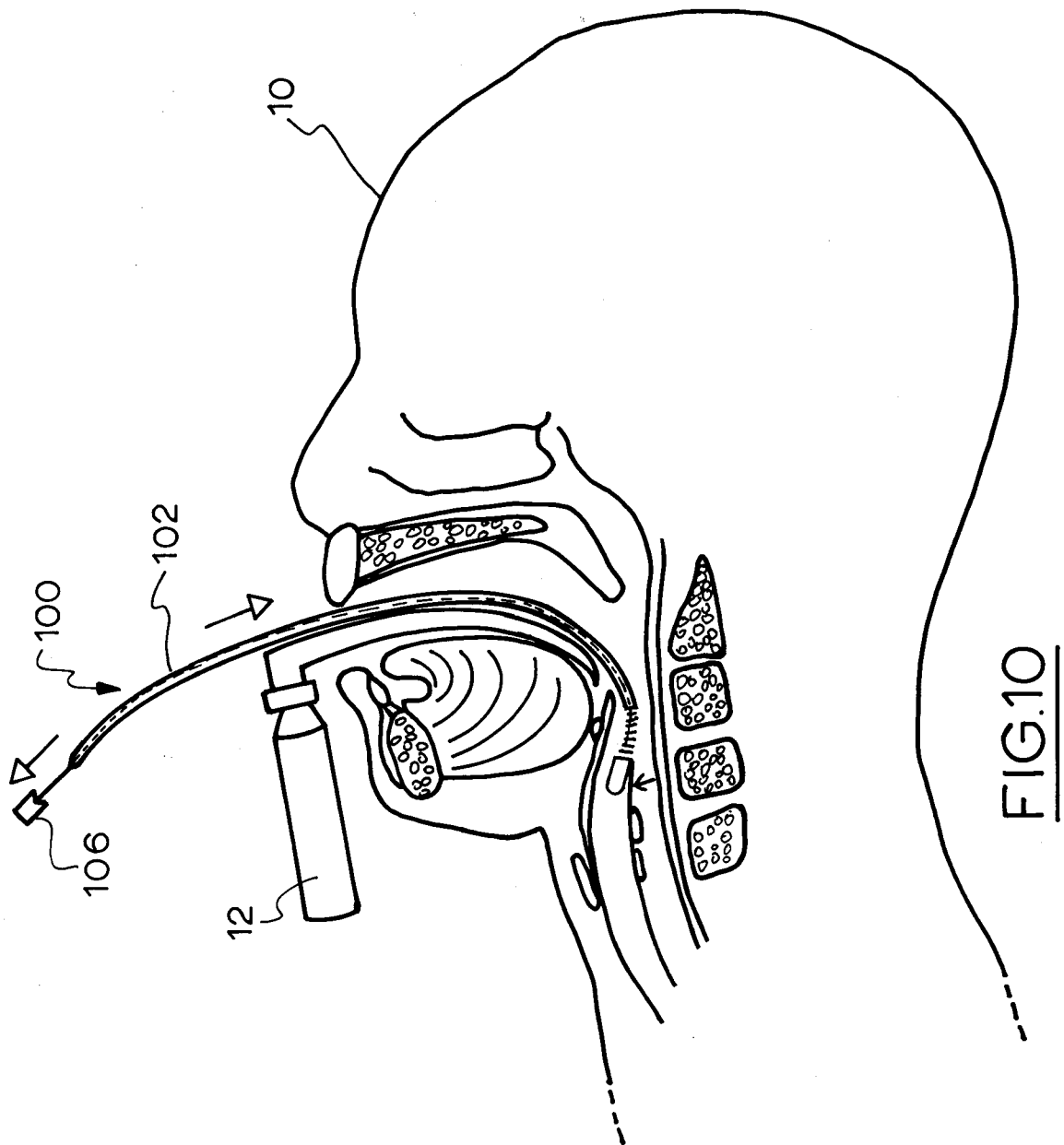


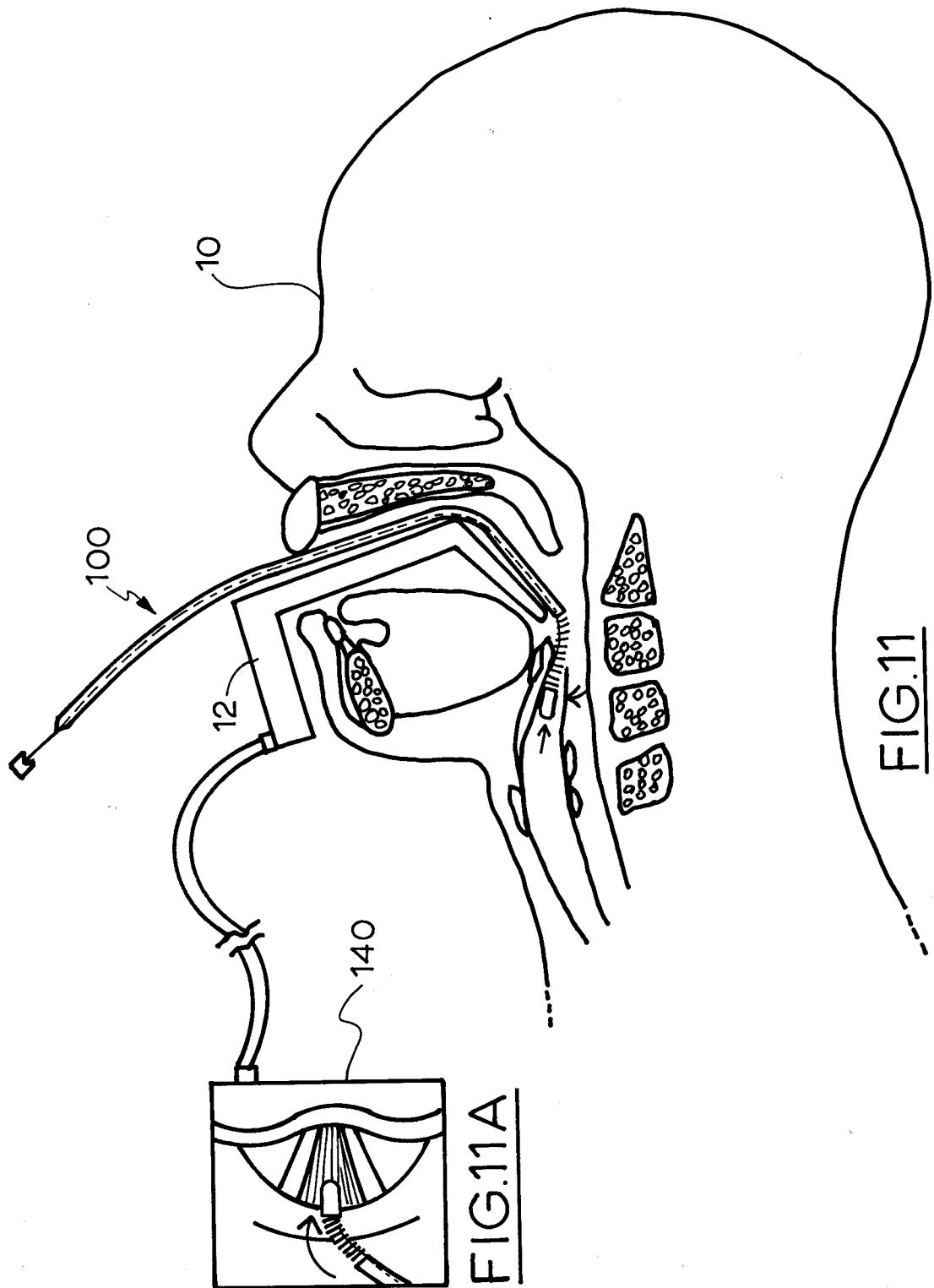
FIG. 5



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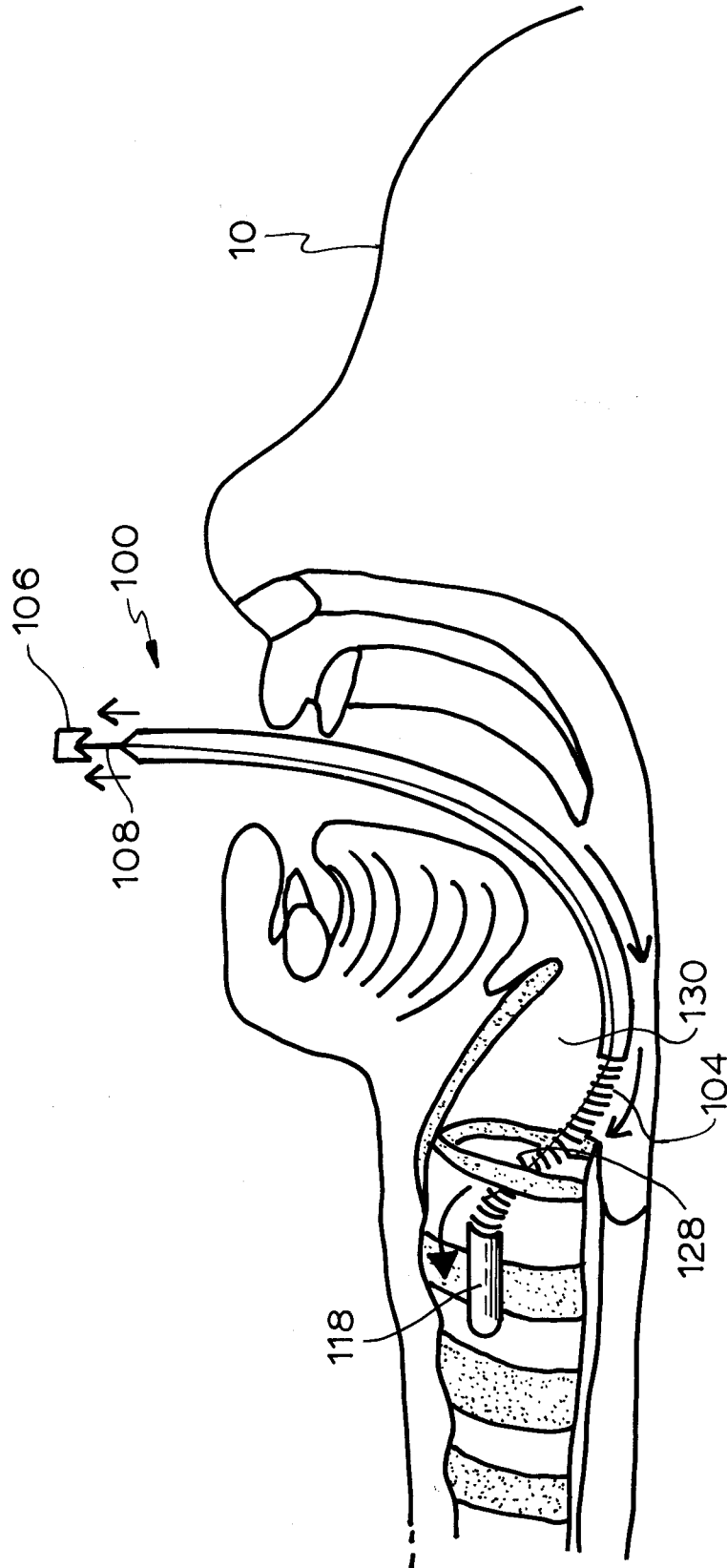


FIG.12

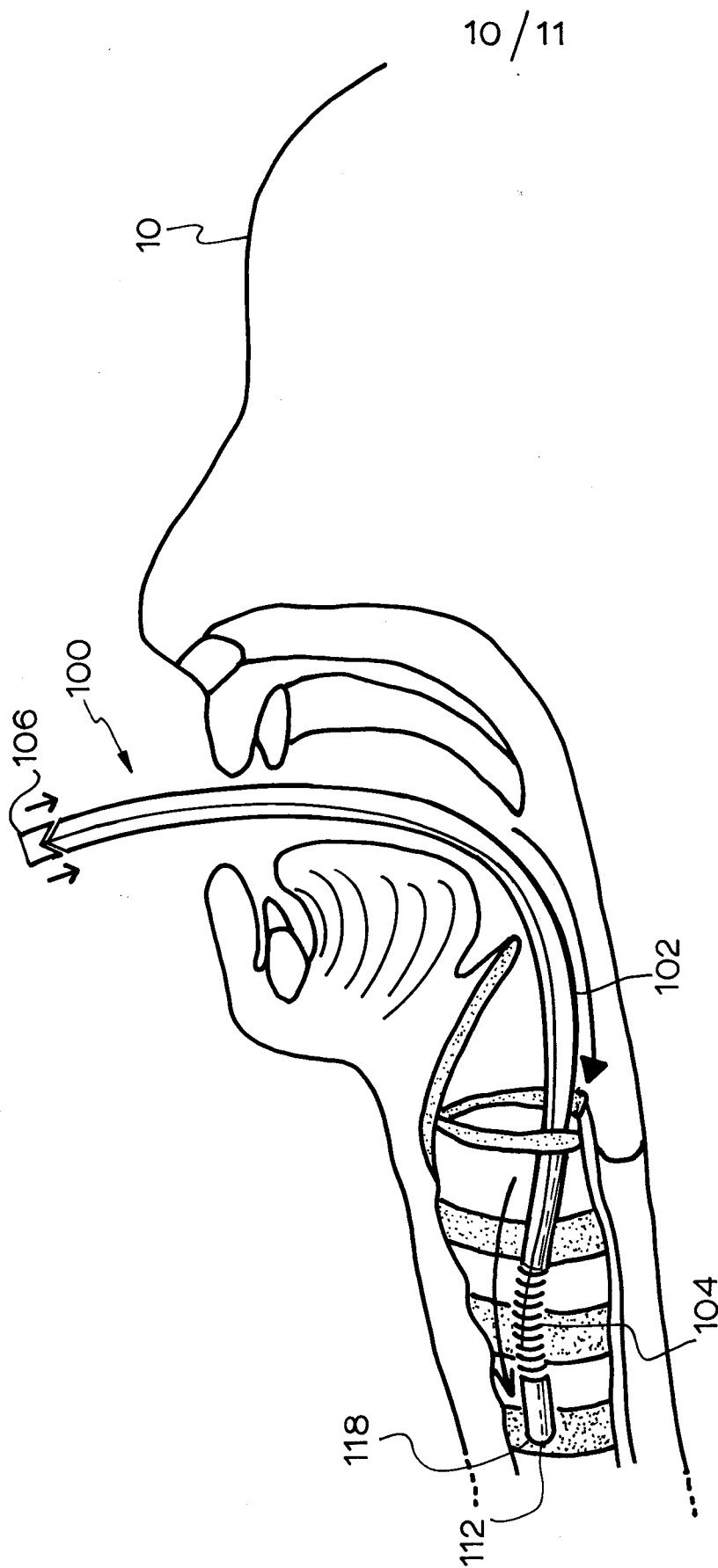


FIG.13

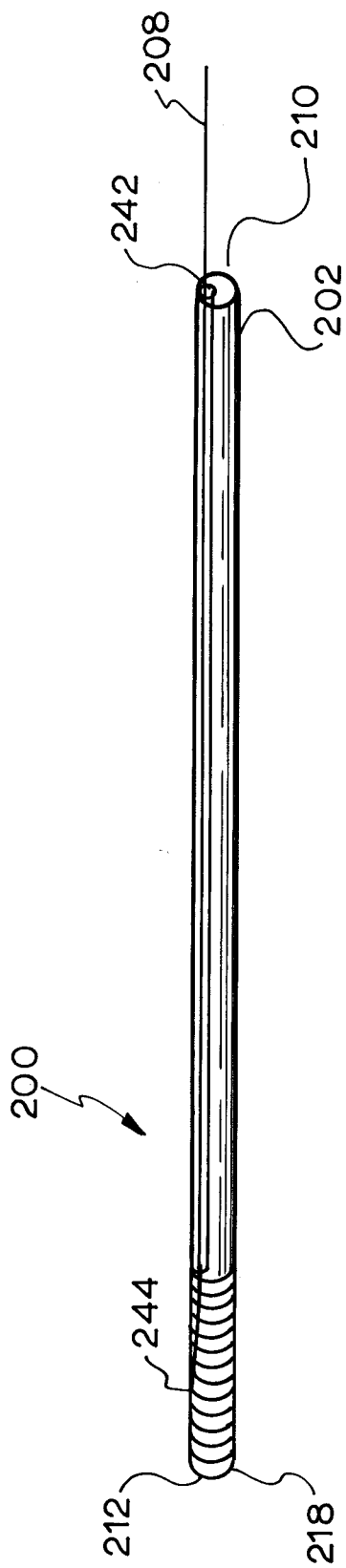


FIG. 14

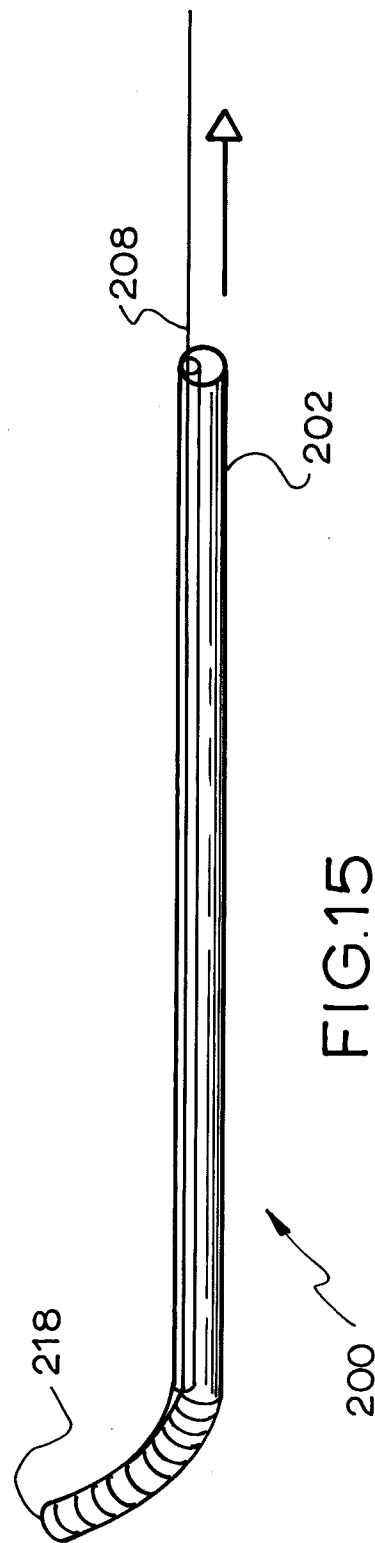


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2015/050047

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/04 (2006.01)

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)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPODOC and A61M16/0418/CC, A61M16/0488/CC and keywords: wire and steer and spring and bougie and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	



Further documents are listed in the continuation of Box C



See patent family annex

* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
7 April 2015

Date of mailing of the international search report
07 April 2015

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INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2015/050047
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0078050 A1 (SCHWARTZ et al.) 29 March 2012 paragraphs 78 - 80, 96 and 105	1 - 3, 5 - 7, 10, 13 - 16, 18, 22, 23, 26, 27, 29, 30, 32, 35, 36
Y	paragraphs 78 - 80, 96 and 105	17
X	WO 2011/119521 A1 (TUFTS MEDICAL CENTER, INC.) 29 September 2011 paragraphs 23 - 29	1, 4 - 7, 10, 13, 14, 19, 20, 22 - 25, 35, 36
Y	paragraphs 23 - 29	2, 3, 17, 26, 27, 29, 30, 32
X	US 2011/0265789 A1 (GABRIEL) 03 November 2011 paragraphs 30 - 35	1, 4 - 7, 10, 13, 14, 16, 18, 22, 23, 35, 36
Y	paragraphs 30 - 35	2, 3, 17, 26, 27, 29, 30, 32
X	US 2013/0255671 A1 (FURMAN et al.) 03 October 2013 paragraphs 22, 33, 34, figures 1 - 3	1, 4 - 16, 18, 21 - 25, 35, 36
Y	paragraphs 22, 33, 34, figures 1 - 3	2, 3, 17, 26 - 34,
Y	US 4622965 A (TEEPL) 18 November 1986 figure 1	2, 3, 26 - 34
Y	WO 2007/138569 A2 (TRUPHATEK INTERNATIONAL LTD) 06 December 2007 figure 6	17

Form PCT/ISA/210 (fifth sheet) (July 2009)

INTERNATIONAL SEARCH REPORT Information on patent family members		International application No. PCT/AU2015/050047	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
US 2012/0078050 A1	29 March 2012		
WO 2011/119521 A1	29 September 2011	US 2013035548 A1	07 Feb 2013
US 2011/0265789 A1	03 November 2011	US 8677990 B2	25 Mar 2014
US 2013/0255671 A1	03 October 2013		
US 4622965 A	18 November 1986		
WO 2007/138569 A2	06 December 2007	EP 2152342 A2	17 Feb 2010
		US 2010108060 A1	06 May 2010
		US 8505531 B2	13 Aug 2013
End of Annex			
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001. Form PCT/ISA/210 (Family Annex)(July 2009)			