# LARYNGEAL MASK AIRWAY DEVICE WITH FIBER OPTIC ASSEMBLY

The present invention relates to a laryngeal mask airway device with a fiber optic assembly. More specifically, the present invention relates to an intubating laryngeal mask airway device with a fiber optic assembly.

The laryngeal mask airway device is a well known device that is useful for establishing airways in unconscious patients. U.S. Patent No. 4,509,514 is one of the many publications that describe laryngeal mask airway devices. Such devices have been in use for many years and offer an alternative to the older, even better known, endotracheal tube. For at least seventy years, endotracheal tubes comprising a long slender tube with an inflatable balloon disposed at the tube's distal end have been used for establishing airways in unconscious patients. In operation, the endotracheal tube's distal end is inserted through the mouth of the patient, past the patient's laryngeal inlet (or glottic opening), and into the patient's trachea. Once so positioned, the balloon is inflated so as to form a seal with the interior lining of the trachea. After this seal is established, positive pressure may be applied to the tube's proximal end to ventilate the patient's lungs. Also, the seal between the balloon and the inner lining of the trachea protects the lungs from aspiration (e.g., the seal prevents material regurgitated from the stomach from being aspirated into the patient's lungs).

Although they have been enormously successful, endotracheal tubes suffer from several major disadvantages. The principal disadvantage of the endotracheal tube relates to the difficulty of properly inserting the tube. Inserting an endotracheal tube into a patient is a procedure that requires a high degree of skill. Also, even for skilled practitioners, insertion of an endotracheal tube is sometimes difficult or not possible. In many instances, the difficulty of inserting endotracheal tubes has tragically led to the death of a patient because it was not possible to establish an airway in the patient with sufficient rapidity. Also, inserting an endotracheal tube normally requires manipulations of the patient's head and neck and further requires the patient's

jaw to be forcibly opened widely. These necessary manipulations make it difficult, or undesirable, to insert an endotracheal tube into a patient who may be suffering from a neck injury.

In contrast to the endotracheal tube, it is relatively easy to insert a laryngeal mask airway device into a patient and thereby establish an airway. Also, the laryngeal mask airway device is a "forgiving" device in that even if it is inserted improperly, it still tends to establish an airway. Accordingly, the laryngeal mask airway device is often thought of as a "life saving" device. Also, the laryngeal mask airway device may be inserted with only relatively minor manipulations of the patient's head, neck, and jaw. Further, the laryngeal mask airway device provides for ventilation of the patient's lungs without requiring contact with the sensitive inner lining of the trachea and the size of the airway established is typically significantly larger than the size of the airway established with an endotracheal tube. Also, the laryngeal mask airway device does not interfere with coughing to the same extent as endotracheal tubes. Largely due to these advantages, the laryngeal mask airway device has enjoyed increasing popularity in recent years.

U.S. Patent Nos. 5,303,697 and 6,079,409 describe examples of a type of prior art device that may be referred to as an "intubating laryngeal mask airway device." The intubating device is useful for facilitating insertion of an endotracheal tube. After an intubating laryngeal mask airway device has been located in the patient, the device can act as a guide for a subsequently inserted endotracheal tube. Use of the laryngeal mask airway device in this fashion facilitates what is commonly known as "blind insertion" of the endotracheal tube. Only minor movements of the patient's head, neck, and jaw are required to insert the intubating laryngeal mask airway device, and once the device has been located in the patient, the endotracheal tube may be inserted with virtually no additional movements of the patient. This stands in contrast to the relatively large motions of the patient's head, neck, and jaw that would be required if the endotracheal tube were inserted without the assistance of the intubating laryngeal mask airway device.

One popular form of intubating laryngeal mask airway device has been marketed commercially for many years as the "Fastrach" by the Laryngeal Mask Company of Cyprus. Figure 1A shows a view of the anterior side of a prior art Fastrach device 100. Figure 1B shows a sectional view of device 100 taken in the direction of the arrows 1B-1B as shown in Figure 1A.

Device 100 includes a rigid steel airway tube 110, a silicone mask portion 130, a rigid steel handle 180, and an inflation line 190. The handle 180 is attached to airway tube 110 near a proximal end 112 of the tube. Mask portion 130 is attached to airway tube 110 at a distal end 114 of the tube. Mask portion 130 includes a dome shaped backplate 132 and an inflatable cuff 134. Mask portion 130 also includes an epiglottis elevator bar 150. One end 152 of bar 150 is attached to the backplate 132. The other end 154 of the bar 150 is "free floating", or not attached to any other portion of the device. The bar 150 is in effect hinged to the rest of the mask portion. Figures 1A and 1B show bar 150 in its resting position (i.e., the position assumed by the bar 150 when no external forces are acting on the bar 150).

In operation, cuff 134 is deflated, and the mask portion is then inserted through the patient's mouth into the patient's pharynx, while the proximal end 112 of the airway tube and the handle 180 remain outside of the patient's mouth. The handle 180 may be used for manipulating the device. The cuff 134 is then inflated to form a seal around the patient's glottic opening. After the device 100 is so positioned, a distal opening 117 of the device (shown in Figure 1A) is aligned with the patient's glottic opening and the device provides a sealed airway extending from the proximal end 112 of airway tube 110 to the patient's trachea. When the epiglottis elevator bar 150 is in the resting position shown in Figures 1A and 1B, the bar 150 prevents the patient's epiglottis from falling into the bowl shape defined by the inflated cuff and backplate and consequently prevents the epiglottis from blocking the airway passage provided by the device. Figure 1C shows an endotracheal tube 195 being inserted through device 100. The distal end 196 of the endotracheal tube 195 is inserted into the proximal end 112 of the airway tube

and the endotracheal tube 195 is then advanced until the distal end 196 reaches and then passes through the mask portion 130. As shown, as the distal end 196 of the endotracheal tube 195 passes through the mask portion, it moves the distal end (or "free" end) 154 of bar 150 out of the resting position.

As shown in Figure 1B, the airway tube 110 defines a curved region that extends from a proximal ray 116 to a distal ray 118, the rays 116, 118 meeting at a center of curvature C. As shown in Figures 1B and 1C, the backplate 132 defines a ramp 140. The curvature of the airway tube 110 and the ramp 140 make blind insertion of the endotracheal tube possible. That is, when device 100 is inserted in a patient, the curve of the airway tube and the ramp insure that the distal tip of a subsequently inserted endotracheal tube will be aligned with the trachea when it passes through the distal opening of device 100. The angle theta (θ) defined by rays 116, 118 is approximately one hundred twenty degrees. The ramp 140 adds about seventeen additional degrees to this curve such that an endotracheal tube inserted through the device curves through about one hundred thirty seven degrees.

The Fastrach is a reusable device and may be sterilized (and reused) many times before becoming too worn for reuse. Although the Fastrach has performed very well, there remains a need for improved intubating laryngeal mask airway devices. It is an object of the present invention to provide such devices.

According to the invention there is provided a laryngeal mask airway device, comprising an airway tube extending from a proximal end to a distal end, the airway tube defining an internal passage capable of receiving an endotracheal tube therein, a mask portion coupled to the distal end of the airway tube, the mask portion including an inflatable cuff and defining an opening in fluid communication with the internal passage, the mask portion being insertable through a mouth of a patient to an inserted location within the patient, the cuff being adapted to surround a glottic opening of the patient when inflated and when the mask portion is at the inserted location, and a

fibre optic viewing device having a proximal end and a distal end, the distal end of the fibre optic viewing device being disposed adjacent the distal end of the airway tube to provide a remote view to a user.

Thus, the device includes an optical system for enabling the physician to insure that the distal end of the device is properly aligned with the patient's trachea before inserting an endotracheal tube through the device.

The airway tube may be fabricated from an inexpensive material, such as plastic, instead of steel, so that the device may be used as a disposable device.

The mask portion may include an epiglottis elevator bar, the bar defining an aperture and being positionable in a resting position and an open position, the fibre optic viewing device providing a view of a region that extends through the aperture defined by the bar.

The fibre optic viewing device preferably includes a lens at its distal end, the lens being spaced from the internal passage to avoid contact between the lens and an endotracheal tube inserted in the passage. This helps to avoid damage to the tube by the lens on insertion or withdrawal of the tube.

The mask portion may include a backplate, the backplate defining a ramp, the ramp defining a supporting surface for supporting an endotracheal tube inserted in the passage. This helps to facilitate insertion of the tube. The ramp may include a passage, the or each optical fibre extending through the passage.

The device may comprise means for preventing loose material from an endotracheal tube in the passage from contacting the lens, and the preventing means may be adapted to prevent material scraped from the endotracheal tube on insertion of the tube through the passage, from contacting the lens. Alternatively or additionally, the preventing means may be adapted to prevent loose material scraped from the endotracheal tube on withdrawal of the tube from the passage, from contacting the lens. The preventing means may comprise one or more notch disposed between the lens and the passage. The or each notch may be integrally formed with the backplate.

Alternatively, the or each notch may be defined by a collar disposed on the backplate, the lens of the fibre optic device passing through the aperture of the collar.

Still other objects and advantages of the present invention will become readily apparent to those skilled in the art from the following detailed description and drawings wherein several embodiments are shown and described, simply by way of illustration of the best mode of the invention.

Figure 1A shows an anterior view of a prior art laryngeal mask airway device.

Figure 1B shows a sectional view taken along the line 1B-1B as shown in Figure 1A.

Figure 1C shows an endotracheal tube being inserted through the device shown in Figure 1A.

Figure 2A shows an anterior view of an intubating laryngeal mask airway device constructed according to the invention.

Figure 2B shows a sectional view taken along the line 2B-2B as shown in Figure 2A.

Figure 2C shows a sectional view taken along the line 2C-2C as shown in Figure 2B.

Figure 2D shows a magnified view of the portion of the device enclosed by the dashed circle labeled 2D as shown in Figure 2B.

Figure 3 shows an endotracheal tube being inserted through an intubating laryngeal mask airway device constructed according to the invention.

Figure 2A shows an anterior view of a disposable intubating laryngeal mask airway device 200 constructed according to the invention. Figure 2B shows a sectional view of device 200 taken in the direction of line 2B-2B as shown in Figure 2A. Figure 2C shows a sectional view of device 200 taken in the direction of line 2C-2C as shown in Figure 2B. Figure 2D shows a magnified view of the portion of the device 200 enclosed by the dashed circle 2D shown in Figure 2B.

Device 200 includes a rigid airway tube 210, a silicone mask portion 230, a rigid handle 280, and an inflation line 290. The handle 280 is attached to airway tube 210 near a proximal end 212 of the tube. Mask portion 230 is attached to airway tube 210 at a distal end 214 of the tube. Mask portion 230 includes a dome shaped silicone backplate 232 and an inflatable cuff 234. Mask portion 230 also includes an epiglottis elevator bar 250. One end 252 of bar 250 is attached to the backplate 232. The other end 254 of the bar 250 is "free floating", or not attached to any other portion of the device. As shown in Figure 2B, the airway tube 210 defines a curved region that extends from a proximal ray 216 to a distal ray 218, the rays 216, 218 meeting at a center of curvature C. As shown in Figures 2B and 2C, the backplate 232 defines a ramp 240. As with prior art device 100, the angle theta ($\theta$) defined by rays 216, 218 is about one hundred twenty degrees, and the ramp 240 adds about seventeen degrees to this curve. Different sized mask portions may be attached to the airway tube to adapt the device for larger or smaller patients, and the ramps in the other mask portions can curve by slightly more or less than seventeen degrees.

As shown best in Figure 2C, airway tube 210 defines a central airway passage 215. Central airway passage 215 extends from the proximal end 212 to the distal end 214 of the tube. When device 200 is inserted in a patient and the cuff 234 is inflated, the cuff 234 forms a seal around the patient's glottic opening and the airway passage 215 communicates with the patient's lungs. When the device 200 is inserted in a patient, the handle 280 and the proximal end 212 of the airway tube remain outside of the patient's mouth, and the device provides a sealed airway passage that extends from the proximal end 212 of the airway tube, through passage 215, to the patient's glottic opening.

Comparing Figures 1A-1B and 2A-2B, it will be appreciated that device 200 has many features in common with device 100. Both devices include silicone mask portions, rigid airway tubes, and rigid handles. However, whereas reusable device 100 includes a steel airway tube and a steel handle, device 200 is disposable and includes a plastic (e.g., polycarbonate)

airway tube 210 and a plastic (e.g. polycarbonate) handle 280. The airway tube 210 and handle 280 of device 200 are preferably made from a rigid material such as polycarbonate. Since it is made from rigid plastic instead of steel, the wall of airway tube 210 is thicker than the wall of airway tube 110. The thickness T of the wall of airway tube 210, as shown in Figure 2C, is substantially equal to 1.9 millimeters. The diameter D of the airway passage 215 defined by tube 210, as shown in Figure 2C, is substantially equal to 12.2 millimeters.

Another important difference between devices 100 and 200 is that device 200 includes a fiber optic system 300. Fiber optic system 300 includes a bundle of optical fibers 310 that extend from a proximal end 312 to a distal end, and a lens 314 is mounted to the optical fibers at their distal end. When the device 200 is inserted in a patient, the proximal end 312 of bundle 310 remains outside of the patient's mouth and may be connected to standard viewing devices (e.g., screens or eyepieces). The lens 314 is disposed near ramp 240.

Although the curve of the airway tube and the shape of the ramp generally facilitate blind insertion of an endotracheal tube, the fiber optic system 300 advantageously provides a view of the patient's anatomy that is aligned with the distal end of device 200. This enables alignment between the distal end of the device and the patient's glottic opening to be adjusted before attempting to insert an endotracheal tube through the device 200. If the distal end of the device is not perfectly aligned with the patient's glottic opening, as shown by the fiberoptic view obtained, the handle 280 may be used to make minor adjustments in the position of device 200 to thereby facilitate subsequent insertion of an endotracheal tube. This stands in contrast with prior art devices in which the glottic opening is sought and identified by means of an expensive mechanism built into the fiberoptic cable itself which allows its distal tip to be flexed in a single plane.

As shown best in Figure 2C, in addition to the central airway passage 215, the airway tube 210 also defines a notch 219. Notch 219 is defined in

the wall of tube 210 and is outside of, and does not communicate with, the airway passage 215. Notch 219 houses a portion of the bundle 310 of optical fibers. As shown in Figure 2B, notch 219 extends from a location 330 on the airway tube to the ramp 240. Location 330 is near the junction of handle 280 and tube 210 and is between that junction and the distal end of the tube. As noted above, the bundle 310 of optical fibers extends from proximal end 312 to lens 314. A free section of the bundle 310 extends from proximal end 312, through a hole 282 defined in handle 280, to the point 330. A "housed" or "protected" section of the bundle 310 extends from point 330 to the lens 314.

As shown best in Figures 2A and 2D, the epiglottis elevator bar 250 is "paddle shaped" and the distal end 254 defines an aperture 256. When bar 250 is in its resting position (i.e., when cuff 234 is inflated and no external forces are acting on bar 250), the lens 314 of fiber optic system 300 is aligned with aperture 256 so that the bar 250 does not occlude the view provided by the lens.

In Figure 2C, the apex of the airway tube 210 is indicated at 340. Apex 340 is the point of the tube that will be contacted by the patient's upper teeth when the device is inserted in a patient. As shown in Figure 2C, the notch 219 is offset from the apex 340 in the region of the airway tube near location 330 to insure that the patient's teeth do not contact and damage the bundle 310 of optical fibers. Although the notch 219 is offset from the apex near point 330, as the notch 219 progresses down the tube towards the mask portion, the notch 219 assumes a more central location such that at the distal end, the lens 314 is centrally aligned with the aperture 256 in the epiglottis elevator bar 250 as shown in Figures 2A and 2D.

Bundle 310 of optical fibers generally contains two sets of fibers. One set carries light from the proximal end 312 to the lens so as to illuminate the patient's anatomy. The other set carries light received by lens 314 back to the proximal end so as to provide a view of the patient's anatomy. In the illustrated embodiment, both sets of fibers extend through a single notch 219. However, it will be appreciated that the airway tube may define two notches

and each set of fibers may be housed in its own notch. In such embodiments, the notches can meet at the ramp 240 so that both sets of fibers and the lens are housed in a single aperture extending through the ramp 240.

As shown best in Figure 2D, device 300 also includes a collar 360. The collar 360 is disposed against the distal end of ramp 240 and houses the distal most portion of the bundle 310 and the lens 314. Collar 360 may be fabricated as an integral part of the backplate portion 230. Mask portion 230, which includes the dome shaped backplate 232, ramp 240, collar 360, and cuff 234 may be formed, for example, by injection molding, as a single monolithic part.

Figure 3 shows an endotracheal tube 195 being inserted through device 200. One useful function performed by collar 360 is that it insures that the endotracheal tube 195 always remains spaced apart from the lens 314. The lens 314 typically defines a sharp right angle surface and it is therefore desirable to space the lens 314 away from the endotracheal tube 195 to insure that the lens 314 does not contact, and possibly tear, the cuff of the endotracheal tube 195. Referring back to Figure 2D, collar 360 insures that the lens 314 is spaced apart from a line extending from supporting surface 242 by a distance D. The distance D may be equal to about two millimeters.

In addition to defining a central aperture for housing the distal end of bundle 310 and lens 314, the collar 360 also defines a first notch 370 and a second notch 380. Notches 370 and 380 help protect the lens 314. Lubricant is often applied to the cuff of an endotracheal tube 195 before the tube is inserted through an intubating device as shown in Figure 3. It is desirable to prevent this lubricant from falling onto, and obstructing the view provided by, the lens 314. As an endotracheal tube 195 is inserted through device 200, the notch 370 collects any lubricant that might be scraped off of the tube 195 and thereby prevents that lubricant from falling onto the lens 314. Similarly, as an endotracheal tube 195 is withdrawn through device 200, the notch 380 collects any lubricant that might be scraped off of the tube 195 and again thereby prevents that lubricant from falling onto the lens 314. Since it may

sometimes be necessary to withdraw one endotracheal tube and then insert another, it is desirable to protect the lens 314 from lubricant that may be scraped off of an endotracheal tube as the tube is withdrawn.

The upright edge of notch 380 can be spaced apart from the distal end of collar 360 by about 2.5 millimeters. The upright edge that defines the proximal end of notch 370 may be spaced apart from the distal end of collar 360 by about five millimeters. Notches 370 and 380 may be about 1.5 millimeters deep.

CLAIMS:

1. A laryngeal mask airway device, comprising an airway tube extending from a proximal end to a distal end, the airway tube defining an internal passage capable of receiving an endotracheal tube therein, a mask portion coupled to the distal end of the airway tube, the mask portion including an inflatable cuff and defining an opening in fluid communication with the internal passage, the mask portion being insertable through a mouth of a patient to an inserted location within the patient, the cuff being adapted to surround a glottic opening of the patient when inflated and when the mask portion is at the inserted location, and a fibre optic viewing device having a distal end and a proximal end, the distal end of the fibre optic viewing device being disposed adjacent the distal end of the airway tube to provide a remote view to a user.

2. A device according to claim 1, the mask portion including an epiglottis elevator bar, the bar defining an aperture and being positionable in a resting position and an open position, the fibre optic viewing device providing a view of a region that extends through the aperture defined by the bar.

3. A device according to claim 1 or claim 2, the fibre optic viewing device including a lens at its distal end, the lens being spaced from the internal passage to avoid contact between the lens and an endotracheal tube inserted in the internal passage.

4. A device according to any preceding claim, the mask portion including a backplate, the backplate defining a ramp, the ramp defining a supporting surface for supporting an endotracheal tube inserted in the internal passage.

5. A device according to claim 4, wherein the ramp includes a

central aperture extending there-through, the or each optical fibre extending through said central aperture.

6. A device according to any of claims 3 to 5 comprising means for preventing loose material from an endotracheal tube in the internal passage from contacting the lens.

7. A device according to claim 6, the preventing means being adapted to prevent material scraped from the endotracheal tube on insertion of the tube through the internal passage, from contacting the lens.

8. A device according to claim 6 or claim 7, the preventing means being adapted to prevent loose material scraped from the endotracheal tube on withdrawal of the tube from the internal passage, from contacting the lens.

9. A device according to any one of claims 6 to 8, the preventing means comprising one or more notch disposed between the lens and the internal passage.

10. A device according to claim 9, the or each notch being integrally formed with the backplate.

11. A device according to claim 9, the or each notch being defined by a collar disposed on the backplate, the collar further defining a central aperture, and the lens of the fibre optic device passing through said aperture.