(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 May 2014 (08.05.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/068558 A1

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

(21) **International Application Number**:
PCT/IL2013/050879

(22) **International Filing Date**:
28 October 2013 (28.10.2013)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/719,972 30 October 2012 (30.10.2012) US

(71) **Applicant**: **BRESLAUER LTD.** [IL/IL]; 58b Amal St., P.O Box 10082, 49513 Petach Tikva (IL).

(72) **Inventors**: **BRESLAUER, Haim**; 58b Amal St., P.O Box 10082, 49001 Petach Tikva (IL). **BESHARIM, Shlomo**; Apple 15, 8496500 Omer (IL). **BESHARIM, Eli**; 5 Mishol Hefer St., 8480605 Be'er - Sheva (IL).

(74) **Agents**: **KAFRI, Jonathan** et al.; DR. EYAL BRESSLER LTD., 11 Tuval St., 52522 Ramat Gan (IL).

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

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,

[Continued on next page]

(54) **Title**: AN INTUMASK ASSEMBLY

(57) **Abstract**: The present invention presents an integrated (i) inner tube, and (ii) laryngeal mask device, comprising: (i)an outer laryngeal mask tube (OLT) having proximal portion and distal portion; comprising: a balloon cuff shaped as a laryngeal mask located in said distal portion and an elongated tube in connection with the balloon cuff (TOLT); (ii) an inner tube located within said OLT characterized by a main longitudinal axis and (iii) at least one lateral movement preventing element located circumferentially to said inner tube and between said inner tube and said OLT. Thereby, when the balloon cuff is in a deflated configuration, the thickness of the same is reduced such that said balloon cuff is not protruding from the TOLT.

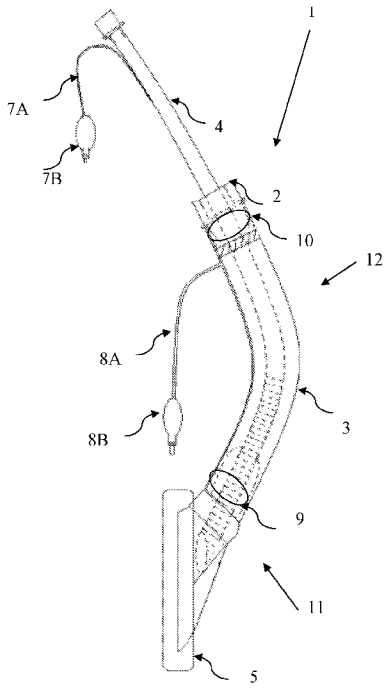

Figure 1

WO 2014/068558 A1

MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

AN INTUMASK ASSEMBLY

FIELD OF THE INVENTION

This invention generally pertains to artificial airway assemblies. In particular, it relates to artificial airway assemblies in which the airway tube is designed for ease of function and placement, and for ensuring that the airway assembly is secured in the correct position.

BACKGROUND OF THE INVENTION

US patent application 2003192548 discloses a laryngeal mask tube which consists of a dual-airway tube, a mask with an inflatable bladder and an inflation indicator device. The dual-airway tube comprises a simplified primary tube and secondary tube integrally combined. The primary tube communicates with the mask to guide gas into the body of a patient and the secondary tube communicates between with the bladder and the inflation indicator device to inflate the bladder and monitor the inflation. Moreover, two ribs are formed in the mask to prevent blockage of the primary tube, and a tongue is formed inside the bladder to prevent the bladder from folding and preventing a seal around the larynx. All of this ensures that the laryngeal mask airway is convenient and efficient to use.

US patent application 2004089307 discloses an artificial airway device comprising a laryngo-pharyngeal mask which includes an expandable masking ring of roughly elliptical shape. The expandable mask sealingly surrounds the laryngeal inlet when expanded, to obstruct communication between the laryngeal inlet and the esophagus. One or more airway tubes connected to the mask provide for fluid flow to a portion of the mask facing the laryngeal inlet when the mask sealingly surrounds the laryngeal inlet. A gastro-tube connected to the mask is bonded along most of its length to the airway tube and provides a fluid flow-path to the surface of the mask facing the esophagus when the mask sealingly surrounds the laryngeal inlet. The distal end of the gastro tube passes through the masking ring at its narrower distal region where, when installed in a patient, it abuts against the esophagus; and the distal portion of the gastro tube flattens when the mask is deflated to facilitate smooth

passage behind the larynx during insertion through the mouth and throat of the patient.

US patent 4,681,094 discloses a laryngoscope comprising a disposable blade unit including two full length blades releasably interconnected along the length thereof to define a tubular passage. A reusable handle unit removably receives one end of the blade unit and retains the blades thereof. The blade unit includes an inflatable balloon expandable against the roof of the mouth to center an inserted laryngoscope and effect movement thereof against the tongue and epiglottis. A pair of suction channels are defined through the blade unit and communicated with the interior of the tubular passage at the leading end thereof. The handle unit includes means for communicating the balloon and suction passages with sources of positive and negative air pressure respectively. The handle unit also mounts illuminating means and a selectively usable adapter for accommodating a hand–manipulable air bag for emergency respiration directly through the laryngoscope.

PCT application WO2004006746 discloses a device for the lateral separation of the air passages of patients or for single-lung ventilation during thoracic surgery. The device comprises a laryngeal mask, upstream of the larynx of the patient, in which a first tube is integrated for lung ventilation. The aim of the invention is to develop a device which enables the lateral separation of the air passages of the patient, or single-lung ventilation, in a safe and effective manner, and which enables the disadvantages of the double lumen tube used until now and the bronchus blocker available until now to be avoided. According to this invention, in addition to the laryngeal mask in which the first tube is integrated, one such device comprises a second tube which can be introduced into the air passages via the first tube.

These inventions are not guaranteed to prevent accidental insertion of the laryngeal mask into the esophagus or to prevent damage to the vocal cords. A laryngeal mask assembly that comprises active means for manipulating the tubing into the trachea still remains a long-standing but unmet need.

Furthermore, it is still a long-standing but unmet need to provide a laryngeal mask assembly without the need to detach the laryngeal mask. In other words, it would be advantageous if there were an integrated laryngeal mask assembly.

SUMMARY OF THE INVENTION

There is provided in accordance with a preferred embodiment of the present invention an integrated *(i)* tubus, and *(ii)* laryngeal mask device, comprising: (a)an outer laryngeal mask tube (OLT) having proximal portion and distal portion; comprising: (i)a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located in the distal portion; the balloon in a fluid connection with an inflating means, located at the proximal end; and,(ii)an elongated tube in connection with the balloon cuff (TOLT);

(b)an inner tube (tubus) located within the OLT; the tubus is characterized by a main longitudinal axis; and,

(c)at least one lateral movement preventing element located circumferentially to the tubus and between the tubus and the OLT; adapted both *(i)* to prevent lateral movement of the tubus with respect to the OLT, such that contamination of the environment between the tubus and the OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT, in a manner that a seal is provided in the inner volume between the OLT and the tubus ,wherein, when the balloon cuff is in the deflated configuration, the thickness of the same is reduced such that the balloon cuff is not protruding from the TOLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, additionally comprising a stopper adapted to fixedly secure the tubus to the operating position within the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, additionally comprising a guide wire substantially accommodated along the length of the OLT; the guide wire is located in an inner canal of the laryngeal mask.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the guide wire is adapted for affixing and stabilizing the laryngeal mask within patient's throat .

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the OLT can be easily peeled off by using the guide wire .

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the inflating means is a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is an O-ring.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the sizes of the O-ring are specified by the outside diameter of the tubus and the cross sectional diameter between the tubus and the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the O-ring is an elastomeric O-ring for sealing.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is a balloon ring.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is a gasket which has the structure and characteristic elements enabling the lateral movement preventing element to be placed between the tubus and the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the sealing structure is selected from the group consisting of: a peripheral seal, a radial seal and any combination thereof.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above,

wherein the stopper prevents travel of the tubus lengthwise in the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the introducer as defined above, additionally comprising a maneuvering mechanism adapted to reorient the distal end of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the OLT is further adapted for guiding a working tool to an operating position to view vocal cords and trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, further wherein the OLT guides a working tool in a manner which allows ventilation through the tubus to continue without interruption.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, additionally comprising a second inflatable balloon located at the distal end of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, additionally comprising a second valve for controlling inflation and deflation of the second balloon. There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above,wherein the second balloon is made of a flexible material.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is inflated to its first state when the laryngeal mask is inserted, such that it blocks entry into the esophagus of the TOLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the first state is a state of the tubus which prevents entry of the esophagus into the internal cavity within the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is disposed about one side of, and in physical contact with, the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second balloon is in physical contact with one side of the tubus, whereby upon inflation of the second balloon while the integrated tubus and laryngeal mask device is in place, at least part of the tubus is positioned in a predetermined direction.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the predetermined direction is in the direction of the trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the OLT has flexible walls integral with the balloon cuff of the OLT and the two are in contact when the balloon cuff is deflated.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is deflated to its second state once the tubus is inserted to the correct position, such that it provides no substantial obstruction within the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second state is a state in which the internal cavity within the OLT is substantially open.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is an expansible member made of an elastic material.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is attached to the OLT and communicates with an inflation lumen extending along the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the OLT is fixedly secured to the operating position of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is disposed externally to the flexible airway.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is disposed within the flexible airway.

There is further provided in accordance with a preferred embodiment of the present invention the integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is integrated within the flexible airway.

There is provided in accordance with a preferred embodiment of the present invention a method for intubating a patient using an integrated tubus and laryngeal mask device, the method comprising a step of: (a)obtaining an integrated *(i)* tubus and, *(ii)* laryngeal mask device, comprising: (i)an outer laryngeal mask tube (OLT) having proximal end and distal portion; comprising: (1)a laryngeal mask with integral balloon cuff, having at least one inflated configuration and at least one deflated configuration, located in the distal portion and in fluid connection with an inflating means located at the proximal end of the OLT; and,(2) a longitudinal tube in communication with the balloon cuff;

(ii) an inner tube (tubus) located within the OLT; the tubus characterized by a main longitudinal axis; and,

(iii) at least one lateral movement preventing element located circumferentially to the tubus and between the tubus and the OLT; adapted to both *(i)* prevent lateral movement of the tubus with respect to the OLT such that a contact-free environment between the tubus and the OLT is provided; and *(ii)* allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT; sealing the inner volume between the tube of the OLT and the tubus such that contamination of the volume is prevented;

(b) inserting the laryngeal mask in its deflated configuration into the mouth of a patient;(c) positioning the laryngeal mask adjacent to the larynx, (d) inflating the inserted balloon cuff in patient's larynx, (e) fixedly securing the tubus to the distal portion of the OLT and (f) deflating the balloon cuff, wherein, when the balloon cuff is deflated, the thickness of the same is reduced such that the balloon cuff is substantially in contact with the tube of the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of initiating ventilation of the patient via the proximal end.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of moving a working tool through the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of moving the working tool beyond the mask and into the trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the integrated tubus and laryngeal mask device further comprises an airway-directing mechanism disposed about one side of the tubus, the method further comprising a step of at least partially maneuvering the airway-directing mechanism whereby the tubus is directed toward the trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of fixedly securing the OLT to the operating position of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the OLT is further adapted for guiding the working tool to an operating position to view vocal cords and trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of providing a second balloon disposed about, and in physical contact with, one side of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of, upon inflation of the inflatable balloon while the tubus is in place, directing at least part of the integrated tubus and laryngeal mask device in the direction of the trachea of the patient.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of disposing the second inflatable balloon externally to the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a step of disposing the second inflatable balloon within the flexible airway.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising step of maneuvering and reorienting the distal end of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a stopper adapted to fixedly secure the tubus in the operating position of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a guide wire substantially accommodated along the length of the OLT; the guide wire is located in an inner canal of the laryngeal mask.

There is further provided in accordance with a preferred embodiment of the present invention the the method as defined above, wherein the guide wire is adapted for affixing and stabilizing the laryngeal mask within patient's throat .

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the OLT can be easily peeled off by using the guide wire .

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the valve is a pilot balloon connected to an inflation lumen extending along the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the lateral movement preventing element is an O-ring.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the O-rings has sizes specified by the outside diameter of the tubus and the cross sectional diameter between the tubus and the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the O-ring is an elastomeric O-ring for sealing.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the lateral movement preventing element is ring-type balloon.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the lateral movement preventing element is any type of a gasket which has the structure and characteristics to be placed between the tubus and the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the sealing structure is selected from the group consisting of: a peripheral seal, a radial seal, and any combination thereof.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the stopper is adapted to prevent travel of the tubus lengthwise in the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the stopper has size, shape and mechanism to reinforce the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a second valve for controlling inflation and deflation of the second balloon.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the balloon cuff is made of a flexible material.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein, when inserting the tubus, the inflation of the balloon cuff to its first state blocks entry of the tubus into the esophagus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the first state is a state of the integrated tubus and laryngeal mask device which prevents entry of the esophagus into the internal cavity within the mask.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the second balloon is in physical contact with one side of the tubus, whereby, upon inflation of the second balloon while the OLT is in place, at least part of the tubus is directed in a predetermined direction.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the OLT tube has flexible walls integral with the cuff balloon of the OLT; the OLT walls and the cuff balloon walls being substantially in contact when the cuff balloon is deflated.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the balloon is deflated to its second state once inserted to and secured in the correct position, such that it provides no substantial obstruction within the mask.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the second state is a state in which the internal cavity within the mask is substantially open.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the second balloon and balloon cuff are expansible members made of an elastic material.

There is provided in accordance with a preferred embodiment of the present invention a method of producing an integrated tubus and laryngeal mask device, comprising steps of: (a)providing an outer laryngeal mask tube (OLT) having proximal end and distal portion having: *(i)* a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located in the distal portion; the balloon in a fluid connection with an inflating means, located at the proximal end, and an elongated tube in connection with the balloon cuff (TOLT); *(ii)* an inner tube (tubus); the tubus characterized by a main longitudinal axis*; (iii)* at least one lateral movement preventing element,
(b)locating the tubus within the OLT (c)positioning the lateral movement preventing element circumferentially to the tubus and between the tubus and the OLT, wherein, the balloon cuff in its deflated configuration is not protruding from the TOLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the lateral movement preventing element is adapted both *(i)* to prevent lateral movement of the tubus with respect to the OLT, such that contamination of the environment between the tubus and the OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT, in a manner that a seal is provided for the inner volume between the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising the step of positioning a stopper at the proximal end of the OLT.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising a guide substantially accommodated along the length of the OLT; the guide wire is located in an inner canal of the laryngeal mask.

There is further provided in accordance with a preferred embodiment of the present invention the the method as defined above, wherein the guide wire is adapted for affixing and stabilizing the laryngeal mask within patient's throat .

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the OLT can be easily peeled off by using the guide wire .

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the tubus additionally comprises a second inflatable balloon.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, additionally comprising the step of sealing the inner volume between the OLT and the tubus with the lateral movement preventing element.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the seal is a peripheral seal.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the seal is a radial seal.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the inflating means is a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the second balloon is in fluid connection with a second inflating means located at the proximal end of the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, wherein the second inflating means is

a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

There is further provided in accordance with a preferred embodiment of the present invention the method as defined above, further wherein the inflating means located at the proximal end is in fluid connection with the lateral movement preventing element.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be implemented in practice, a few preferred embodiments will now be described, by way of non-limiting example only, with reference to be accompanying drawings, in which:

FIG. 1 is a cross-sectional view of a laryngeal mask assembly according to one embodiment of the invention;

FIG. 2 is a cross-sectional view of a laryngeal mask assembly in its operating position according to a second embodiment of the invention;

FIG. 3 is a cross-sectional view, of a laryngeal mask assembly in its operating position according to the embodiment of the invention illustrated in FIG. **2**;

FIG 4 illustrates a flow chart of a method for intubating a patient using a laryngeal mask assembly according to the embodiment of the invention; and

FIG 5 illustrates a flow chart of a method for producing a laryngeal mask assembly according to the embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, various aspects of the invention will be described. For the purposes of explanation, specific details are set forth in order to provide a thorough understanding of the invention. It will be apparent to one skilled in the art that there are other embodiments of the invention that differ in details without affecting the essential nature thereof. Therefore the invention is not limited by that which is illustrated in the figures and described in the specification, but only as indicated in the accompanying claims, with the proper scope determined only by the broadest interpretation of the claims.

Reference is now made to **FIG. 1,** which shows a cross-sectional view of an artificial airway assembly before insertion according to one embodiment **1** of the present invention.

In preferred embodiments, the integrated tubus and laryngeal mask device **1** comprises an outer laryngeal mask tube (OLT) **4** having proximal portion **12** and distal portion **11**. The OLT comprises a balloon cuff **5** in a communication with a longitudinal tube **3**. The balloon cuff **5** is shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, and is in fluid connection with an inflating means. The balloon cuff is located at the distal end **11** of the OLT. The balloon cuff is an expansible member, made of an elastic material, which has an approximately toroidal shape.

The integrated tubus and laryngeal mask device **1** further comprises a flexible airway tube (i.e., a tubus) **4** as an inner tube (tubus) located within the OLT 3. The tubus is characterized by a main longitudinal axis. The balloon cuff is connected to an inflation lumen **8A** extending along the OLT and the tubus with an inflatable valve **8B**, such as a pilot balloon, located at the inflation lumen edge. The valve assembly **8B** is in fluid connection with the OLT and allows air to pass in and out of the OLT balloon cuff, allowing for easier insertion, as the OLT balloon cuff need not be inflated until it is already substantially in place.

The OLT is adapted to conform to the space immediately adjacent to the larynx of the patient. In preferred embodiments, the OLT is constructed of a resilient flexible biocompatible material in the form of a peripheral ring capable of defining a hollow space, capable of being inflated and deflated to accommodate the space

adjacent to the larynx. When installed, the OLT adopts a configuration substantially conforming to the shape of the laryngeal inlet.

The integrated tubus and laryngeal mask device **1** further comprises at least one lateral movement preventing element **9-10** located circumferentially to the tubus and between the inner lumen of the tubus and the OLT. The lateral movement preventing element is adapted to prevent lateral movement of the tubus with respect to the OLT such that a contact-free environment between the tubus and the OLT is provided. The lateral movement preventing element is further adapted to allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT. The main goal of the lateral movement preventing element is to create a peripheral sealing or a radial sealing of the inner volume between the tube of the OLT and the tubus, preventing any contamination of the inner tube or infection of the throat or esophagus. The lateral movement preventing element **9-10** is selected from the group consisting of: an O ring, an inflated balloon ring or any gasket which has the structure and character to create a peripheral seal or a radial seal in between the tubus and the OLT. The O-ring acts as a mechanical gasket. It has the shape of a torus, and is designed as a loop of elastomer with a disc-shaped cross-section. The lateral movement preventing element can be positioned in the distal portion or/and in the proximal portion of the device. The lateral movement preventing element can be activated by an inflation valve assembly **7** if inflation or deflation of the element is required.

The integrated tubus and laryngeal mask device **1** further comprises a stopper **2** as an engagement part located in the proximal portion. The stopper fixedly secures the tubus to an operating position inside the OLT. The stopper prevents the tubus from traveling lengthwise in the OLT tube when ventilation is performed.

The integrated tubus and laryngeal mask device **1** further comprises a guide wire substantially accommodated along the length of the OLT. The guide wire is adapted for immutability and easy intubation of the laryngeal mask by providing a stiffness characters to the OLT. Further more, the guide wire enables the laryngeal mask to be flexible and rigid simultaneously such that it will not collapse or fold when inserted to patient's delivery system. The guide wire is positioned within an inner canal of the laryngeal mask.

The guide wire is further adapted for affixing and stabilizing the laryngeal mask within patient's throat . Further more, the OLT can be easily removed using the

guide wire such that the OLT is peeled off from patient's throat whilst the tubus remains within the patient's throat.

Reference is now made to **FIG. 2,** which shows a cross-sectional view of the integrated tubus and laryngeal mask device of a second embodiment of the invention. In this embodiment, the tubus is inserted into patient's trachea until it is substantially in place order to intubate a patient. The tubus **4** is inserted into the mouth of the patient. The OLT **5** is positioned adjacent to the larynx, thus sealing at least partially the integrated tubus and laryngeal mask device for communication exclusively through the laryngeal inlet.

In another embodiment of the invention, air is injected into the OLT balloon cuff **5** via the valve assembly **8A-8B**. The distal end of the fully inflatable cuff formation prevents the more rigid distal end of the OLT from catching the inside of the throat and subjecting the patient to undesirable forces.

In another embodiment of the invention, a valve assembly **7A-7B** is presented. The valve assembly **7A-7B** comprises an inflation lumen **7A** and an operation valve **7B** located within the edge of the inflation lumen. The valve assembly is in physical connection with the tubus. The valve **7A-7B** controls the inflating and deflating activation respectively of a second balloon attached to the distal end of the tubus when the integrated tubus and laryngeal mask device is substantially in place. Air can be also injected into the second balloon **6** by use of a syringe, but any means known in the art may be used instead.

Reference is now made to **FIG. 3,** which shows a cross-sectional view of the integrated tubus and laryngeal mask device of a third embodiment of the invention. In this embodiment, the tubus is in its operating position as it is used to intubate a patient. The OLT balloon cuff **5** is positioned adjacent to the larynx, thus sealing at least partially the integrated tubus and laryngeal mask device for communication exclusively through the laryngeal inlet as it is positioned inside the trachea in order to start the ventilation process on a patient. When the laryngeal mask is in its insertion position, the balloon cuff **5** is inflated to its first state so that it blocks entry into the esophagus of the TOLT. Once inserted to the correct position, the balloon cuff **5** is deflated to its second state so that it provides no substantial obstruction within the mask 5.

In **FIG. 3**, the tubus is fixedly secured inside the patient's trachea thus allowing deflation of the balloon cuff using the valve assembly **8A-8B**. When air is withdrawn and released from the inflation lumen **8A**, the resilience of the balloon **5** causes it to retract. Its thickness is reduced so that the balloon cuff lies flat against the surface of the OLT and adjacent to the OLT tube's walls, resulting an integration of the cuff with the tube of the OLT. In a preferred embodiment, the OLT tube is integrated with a deflated cuff balloon (masking ring) which provides a seal around the laryngeal inlet with an adjacent independent airway supply to the patient's lungs.

In another embodiment of the invention, **FIG 3** further presents a second balloon **6** disposed about one side, which is inflated by supplying air or other fluid along the inflation lumen **7A** in the usual way, so that the balloon expands to substantially fill the cavity of the trachea. The second balloon **6** is in physical contact with the tubus' distal end. The second balloon **6** may be of any appropriate biocompatible rubber-like material. In preferred embodiments of the invention, it is disposed on the outer circumference of the tubus. In other embodiments, it is disposed within tubus.

After insertion of the integrated tubus and laryngeal mask device, an additional working tool may be inserted through the proximal portion of the OLT and into the trachea in a position from which a viewing device (e.g. a fiber optic device) can be used to observe the vocal cords.

In another embodiment, the artificial airway assembly defined above is provided with a pneumatic airway-directing mechanism which comprises at least one inflatable balloon useful to direct at least part of the integrated tubus and laryngeal mask device to a predetermined location. Additionally, or alternatively, the integrated tubus and laryngeal mask device defined above, is provided with a mechanical airway-directing mechanism which comprises at least one maneuverable effecter useful to direct at least part of the flexible airway to a predetermined location. The integrated tubus and laryngeal mask device which comprises an integrated mechanism, namely a pneumatic and mechanical mechanism, is possible.

It is another object of the present invention to provide an integrated *(i)* tubus, and *(ii)* laryngeal mask device, comprising: *(a)* an outer laryngeal mask tube (OLT) having proximal portion and distal portion; comprising: *(i)* a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located in the distal portion. The balloon is in a fluid connection with

an inflating means, located at the proximal end; and, *(ii)* an elongated tube in connection with the balloon cuff (TOLT); *(b)* an inner tube (tubus) located within the OLT; the tubus is characterized by a main longitudinal axis; and, *(c)* at least one lateral movement preventing element located circumferentially to the tubus and between the tubus and the OLT; adapted both *(i)* to prevent lateral movement of the tubus with respect to the OLT, such that contamination of the environment between the tubus and the OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT, in a manner that a seal is provided in the inner volume between the OLT and the tubus; wherein, when the balloon cuff is in the deflated configuration, the thickness of the same is reduced such that the balloon cuff is not protruding from the TOLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device, additionally comprising a stopper adapted to fixedly secure the tubus to the operating position within the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device, additionally comprising a guide wire substantially accommodated along the length of the OLT; the guide wire is located in an inner canal of the laryngeal mask.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the inflating means is a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is an O-ring.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the sizes of the O-rings are specified by the outside diameter of the tubus and the cross sectional diameter between the tubus and the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the O-ring is an elastomeric O-ring for sealing.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is a balloon ring.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the lateral movement preventing element is any type of gasket which has the structure and characteristic elements enabling the lateral movement preventing element to be placed between the tubus and the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the sealing structure is selected from the group consisting of a peripheral seal, a radial seal, and any combination thereof.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the stopper prevents travel of the tubus lengthwise in the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, additionally comprising a maneuvering mechanism adapted to reorient the distal end of the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the OLT is further adapted for guiding a working tool to an operating position to view vocal cords and trachea of the patient.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, further wherein the OLT guides a working tool in a manner which allows ventilation through the tubus to continue without interruption.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, additionally comprising a second inflatable balloon located at the distal end of the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, additionally comprising a second valve for controlling inflation and deflation of the second balloon.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second balloon is made of a flexible material.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is inflated to its first

state when the laryngeal mask is inserted, such that it blocks entry into the esophagus of the TOLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the first state is a state of the tubus which prevents entry of the esophagus into the internal cavity within the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the inflatable balloon is disposed about one side of, and in physical contact with, the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second balloon is in physical contact with one side of the tubus, whereby upon inflation of the second balloon while the integrated tubus and laryngeal mask device is in place, at least part of the tubus is positioned in a predetermined direction.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the predetermined direction is in the direction of the trachea of the patient.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the OLT has flexible walls integral with the balloon cuff of the OLT and the two are substantially in contact when the balloon cuff is deflated.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is deflated to its second state once the tubus is inserted to the correct position, such that it provides no substantial obstruction within the OLT.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second state is a state in which the internal cavity within the OLT is substantially open.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is an expansible member made of an elastic material.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the balloon cuff is attached to the OLT and communicates with an inflation lumen extending along the OLT and the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the OLT is fixedly secured to the operating position of the tubus.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is disposed externally to the flexible airway.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is disposed within the flexible airway.

It is another object of the present invention to provide an integrated tubus and laryngeal mask device as defined above, wherein the second inflatable balloon is integrated within the flexible airway.

Fig 4 illustrates a flow chart of a method for intubating a patient using a laryngeal mask assembly of the present invention. It is another object of the present invention to provide a method for intubating a patient using an integrated tubus and laryngeal mask device, the method comprising a step of: (a) obtaining an integrated (I) tubus and (II) laryngeal mask device **100**, comprising: (i) an outer laryngeal mask tube (OLT) having proximal end and distal portion, comprising: (a) a laryngeal mask with integral balloon cuff, having at least one inflated configuration and at least one deflated configuration, located in the distal portion and in fluid connection with an inflating means located at the proximal end of the OLT; and, (b) a longitudinal tube in communication with the balloon cuff;

(ii) an inner tube (tubus) located within the OLT, the tubus characterized by a main longitudinal axis, and (iii) at least one lateral movement preventing element located circumferentially to the tubus and in between the tubus and the OLT; adapted to both (*i*) prevent lateral movement of the tubus with respect to the OLT such that a contact-free environment between the tubus and the OLT is provided, and (*ii*) allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT; sealing of the inner volume between the tube of the PLT and the tubus such that contamination of the volume is prevented;

(b) inserting the laryngeal mask in its deflated configuration into the mouth of a patient **110**, (c) positioning the balloon mask adjacent to the larynx **120**, (d) inflating the inserted balloon cuff in patient's larynx **130**, (e) fixedly securing the tubus to the distal portion of the OLT **140**; and (f) deflating the balloon cuff **150**;

wherein, when balloon cuff is deflated, the thickness of the same is reduced such that the balloon cuff is substantially in contact with the tube of the OLT.

It is another object of the present to provide a method for intubating a patient using an integrated tubus and laryngeal mask device additionally comprising a step of initiating ventilation of the patient via the proximal end.

It is another object of the present to provide a method for intubating a patient using an integrated tubus and laryngeal mask device, additionally comprising a step of moving a working tool through the OLT

It is another object of the present invention to provide the method as defined above, additionally comprising a step of moving the working tool beyond the mask and into the trachea of the patient.

It is another object of the present invention to provide the method as defined above, wherein the integrated tubus and laryngeal mask device further comprises an airway-directing mechanism disposed about one side of the tubus, the method further comprising a step of at least partially maneuvering the airway-directing mechanism whereby the tubus is directed toward the trachea of the patient.

It is another object of the present invention to provide the method as defined above, additionally comprising a step of fixedly securing the OLT to the operating position of the tubus.

It is another object of the present invention to provide the method as defined above, wherein the OLT is further adapted for guiding the working tool to an operating position to view vocal cords and trachea of the patient.

It is another object of the present invention to provide the method as defined above, additionally comprising a step of providing a second balloon disposed about, and in physical contact with, one side of the tubus.

It is another object of the present invention to provide the method as defined above, additionally comprising a step of, upon inflation of the inflatable balloon while the tubus is in place, directing at least part of the integrated tubus and laryngeal mask device in the direction of the trachea of the patient.

It is another object of the present invention to provide the method as defined above, additionally comprising a step of disposing the second inflatable balloon externally to the tubus.

It is another object of the present invention to provide the method as defined above, additionally comprising a step of disposing the second inflatable balloon within the flexible airway.

It is another object of the present invention to provide the method as defined above, additionally comprising step of maneuvering and reorienting the distal end of the tubus.

It is another object of the present invention to provide the method as defined above, additionally comprising a stopper adapted to fixedly secure the tubus in its operating position.

It is another object of the present invention to provide the method as defined above, additionally comprising a guide wire substantially accommodated along the length of the OLT; the guide wire is located in an inner canal of the laryngeal mask.

It is another object of the present invention to provide the method as defined above, wherein the valve is a pilot balloon connected to an inflation lumen extending along the OLT and the tubus.

It is another object of the present invention to provide the method as defined above, wherein the lateral movement preventing element is an O-ring.

It is another object of the present invention to provide the method as defined above, wherein the O-ring has sizes specified by the outside diameter of the tubus and the cross sectional diameter between the tubus and the OLT.

It is another object of the present invention to provide the method as defined above, wherein the O-ring is an elastomeric O-ring for sealing.

It is another object of the present invention to provide the method as defined above, wherein the lateral movement preventing element is ring-type balloon.

It is another object of the present invention to provide the method as defined above, wherein the lateral movement preventing element is any type of a gasket which has the structure and characteristics to be placed between the tubus and the OLT.

It is another object of the present invention to provide the method as defined above, wherein the sealing structure is selected from the group consisting of: a peripheral seal, a radial seal, and any combination thereof.

It is another object of the present invention to provide the method as defined above, wherein the stopper adapted to prevent travel of the tubus lengthwise in the OLT.

It is another object of the present invention to provide the method as defined above, wherein the stopper has the size, shape and mechanism to reinforce the tubus.

It is another object of the present invention to provide the method as defined above, additionally comprising a second valve for controlling inflation and deflation of the second balloon.

It is another object of the present invention to provide the method as defined above, wherein the balloon cuff is made of a flexible material.

It is another object of the present invention to provide the method as defined above, wherein, when inserting the tubus, inflation of the balloon cuff to its first state blocks entry of the tubus into the esophagus.

It is another object of the present invention to provide the method as defined above, wherein the first state is a state of the integrated tubus and laryngeal mask device which prevents entry of the esophagus into the internal cavity within the mask.

It is another object of the present invention to provide the method as defined above, wherein the second balloon is in physical contact with one side of the tubus, whereby, upon inflation of the second balloon while the OLT is in place, at least part of the tubus is directed in a predetermined direction.

It is another object of the present invention to provide the method as defined above, wherein the OLT tube has flexible walls integral with the cuff balloon of the OLT and substantially in contact with them when the cuff balloon is deflated.

It is another object of the present invention to provide the method as defined above, wherein the balloon is deflated to its second state once inserted to and secured in the correct position, such that it provides no substantial obstruction within the mask.

It is another object of the present invention to provide the method as defined above, wherein the second state is a state in which the internal cavity within the mask is substantially open.

It is another object of the present invention to provide the method as defined above, wherein the second balloon and the balloon cuff are expansible members made of an elastic material.

Fig 5 illustrates a flow chart of a method for producing a laryngeal mask assembly of the present invention. It is another object of the present invention to provide a method of producing an integrated tubus and laryngeal mask device as defined above, comprising steps of: *(a)* providing an outer laryngeal mask tube (OLT)

having proximal end and distal portion **200** having: *(i)* a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located at the distal portion; the balloon in fluid connection with an inflating means, located at the proximal end, and an elongated tube in connection with the balloon cuff (TOLT); *(ii)* an inner tube (tubus); the tubus characterized by a main longitudinal axis; *(iii)* at least one lateral movement preventing element; *(b)* locating the tubus within the OLT **210**, *(c)* positioning the lateral movement preventing element circumferentially to the tubus and in between the tubus and the OLT **220**; wherein the balloon cuff in its deflated configuration is not protruding from the TOLT.

It is another object of the present invention to provide the method as defined above, wherein the lateral movement preventing element is adapted both *(i)* to prevent lateral movement of the tubus with respect to the OLT, such that contamination of the environment between the tubus and the OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of the tubus along the main longitudinal axis with respect to the OLT, in a manner that a seal is provided for the inner volume between the OLT and the tubus.

It is another object of the present invention to provide the method as defined above, additionally comprising the step of positioning a stopper at the proximal end of the OLT.

It is another object of the present invention to provide the method as defined above, wherein the tubus additionally comprises a second inflatable balloon.

It is another object of the present invention to provide the method as defined above, additionally comprising the step of sealing the inner volume between the OLT and the tubus with the lateral movement preventing element.

It is another object of the present invention to provide the method as defined above, wherein the seal is a peripheral seal.

It is another object of the present invention to provide the method as defined above, wherein the seal is a radial seal.

It is another object of the present invention to provide the method as defined above, wherein the inflating means is a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

It is another object of the present invention to provide the method as defined above, wherein the second balloon is in fluid connection with a second inflating means located at the proximal end of the tubus.

It is another object of the present invention to provide the method as defined above, wherein the second inflating means is a pilot balloon valve connected to an inflation lumen extending along the OLT and the tubus.

It is another object of the present invention to provide the method as defined above, further wherein the inflating means located at the proximal end is in fluid connection with the lateral movement preventing element.

CLAIMS

1. An integrated *(i)* tubus, and *(ii)* laryngeal mask device, comprising:

a. an outer laryngeal mask tube (OLT) having proximal portion and distal portion; comprising:

i. a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located in said distal portion; said balloon in a fluid connection with an inflating means, located at said proximal end; and,

ii. an elongated tube in connection with said balloon cuff (TOLT);

b. an inner tube (tubus) located within said OLT; said tubus is characterized by a main longitudinal axis; and,

c. at least one lateral movement preventing element located circumferentially to said tubus and between said tubus and said OLT; adapted both *(i)* to prevent lateral movement of said tubus with respect to said OLT, such that contamination of the environment between said tubus and said OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of said tubus along said main longitudinal axis with respect to said OLT, in a manner that a seal is provided in the inner volume between the OLT and the tubus

wherein, when said balloon cuff is in said deflated configuration, the thickness of the same is reduced such that said balloon cuff is not protruding from said TOLT.

2. The integrated tubus and laryngeal mask device according to claim **1**, additionally comprising a stopper adapted to fixedly secure said tubus to said operating position within said OLT.

3. The integrated tubus and laryngeal mask device according to claim **1**, additionally comprising a guide wire substantially accommodated along the length of said OLT; said guide wire is located in an inner canal of said laryngeal mask.

4. The integrated tubus and laryngeal mask device according to claim **3**, wherein said guide wire is adapted for affixing and stabilizing said laryngeal mask within patient's throat .

5. The integrated tubus and laryngeal mask device according to claim **1**, wherein said OLT can be easily peeled off by using said guide wire .

6. The integrated tubus and laryngeal mask device according to claim **1**, wherein said inflating means is a pilot balloon valve connected to an inflation lumen extending along said OLT and said tubus.

7. The integrated tubus and laryngeal mask device according to claim **1**, wherein said lateral movement preventing element is an O-ring.

8. The integrated tubus and laryngeal mask device according to claim **4**, wherein the sizes of said O-ring are specified by the outside diameter of the tubus and the cross sectional diameter between said tubus and said OLT.

9. The integrated tubus and laryngeal mask device according to claim **4**, wherein said O-ring is an elastomeric O-ring for sealing.

10. The integrated tubus and laryngeal mask device according to claim **1**, wherein said lateral movement preventing element is a balloon ring.

11. The integrated tubus and laryngeal mask device according to claim **1**, wherein said lateral movement preventing element is a gasket which has the structure and characteristic elements enabling said lateral movement preventing element to be placed between said tubus and said OLT.

12. The integrated tubus and laryngeal mask device according to claim **1**, wherein said sealing structure is selected from the group consisting of: a peripheral seal, a radial seal and any combination thereof.

13. The integrated tubus and laryngeal mask device according to claim **2**, wherein said stopper prevents travel of said tubus lengthwise in said OLT.

14. The integrated tubus and laryngeal mask device according to claim **1**, additionally comprising a maneuvering mechanism adapted to reorient the distal end of said tubus.

15. The integrated tubus and laryngeal mask device according to claim **1**, wherein said OLT is further adapted for guiding a working tool to an operating position to view vocal cords and trachea of said patient.

16. The integrated tubus and laryngeal mask device according to claim **1**, further wherein said OLT guides a working tool in a manner which allows ventilation through said tubus to continue without interruption.

17. The integrated tubus and laryngeal mask device according to claim **1**, additionally comprising a second inflatable balloon located at the distal end of said tubus.

18. The integrated tubus and laryngeal mask device according to claim **14**, additionally comprising a second valve for controlling inflation and deflation of said second balloon.

19. The integrated tubus and laryngeal mask device according to claim **14**, wherein said second balloon is made of a flexible material.

20. The integrated tubus and laryngeal mask device according to claim **1**, wherein said balloon cuff is inflated to its first state when the laryngeal mask is inserted, such that it blocks entry into the esophagus of the TOLT.

21. The integrated tubus and laryngeal mask device according to claim **17**, wherein said first state is a state of said tubus which prevents entry of the esophagus into the internal cavity within said OLT.

22. The integrated tubus and laryngeal mask device according to claim **1**, wherein said second inflatable balloon is disposed about one side of, and in physical contact with, said tubus.

23. The integrated tubus and laryngeal mask device according to claim **14**, wherein said second balloon is in physical contact with one side of said tubus, whereby upon inflation of said second balloon while said integrated tubus and laryngeal mask device is in place, at least part of said tubus is positioned in a predetermined direction.

24. The integrated tubus and laryngeal mask device according to claim **20**, wherein said predetermined direction is in the direction of the trachea of said patient.

25. The integrated tubus and laryngeal mask device according to claim **1**, wherein said OLT has flexible walls integral with the balloon cuff of said OLT and the two are in contact when said balloon cuff is deflated.

26. The integrated tubus and laryngeal mask device according to claim **1**, wherein said balloon cuff is deflated to its second state once said tubus is inserted to the correct position, such that it provides no substantial obstruction within said OLT.

27. The integrated tubus and laryngeal mask device according to claim **23**, wherein said second state is a state in which the internal cavity within said OLT is substantially open.

28. The integrated tubus and laryngeal mask device according to claim **1**, wherein said balloon cuff is an expansible member made of an elastic material.

29. The integrated tubus and laryngeal mask device according to claim **1**, wherein said balloon cuff is attached to said OLT and communicates with an inflation lumen extending along said OLT and said tubus.

30. The integrated tubus and laryngeal mask device according to claim **1**, wherein said OLT is fixedly secured to said operating position of said tubus.

31. The integrated tubus and laryngeal mask device according to claim **14**, wherein said second inflatable balloon is disposed externally to said flexible airway.

32. The integrated tubus and laryngeal mask device according to claim **14**, wherein said second inflatable balloon is disposed within said flexible airway.

33. The integrated tubus and laryngeal mask device according to claim **14**, wherein said second inflatable balloon is integrated within said flexible airway.

34. A method for intubating a patient using an integrated tubus and laryngeal mask device, said method comprising a step of:

a. obtaining an integrated *(i)* tubus and, *(ii)* laryngeal mask device, comprising:

i. an outer laryngeal mask tube (OLT) having proximal end and distal portion; comprising:

(1) a laryngeal mask with integral balloon cuff, having at least one inflated configuration and at least one deflated configuration, located in said distal portion and in fluid connection with an inflating means located at said proximal end of said OLT; and,

(2) a longitudinal tube in communication with said balloon cuff;

ii. an inner tube (tubus) located within said OLT; said tubus characterized by a main longitudinal axis; and,

iii. at least one lateral movement preventing element located circumferentially to said tubus and between said tubus and said OLT; adapted to both *(i)* prevent lateral movement of said tubus with respect to said OLT such that a contact-free environment between said tubus and said OLT is provided; and *(ii)* allow longitudinal reciprocating movement of said tubus along said main longitudinal axis with respect to said OLT; sealing the inner volume between said tube of said OLT and said tubus such that contamination of said volume is prevented;

b. inserting said laryngeal mask in its deflated configuration into the mouth of a patient;

c. positioning said laryngeal mask adjacent to the larynx;

d. inflating said inserted balloon cuff in patient's larynx;

e. fixedly securing said tubus to said distal portion of said OLT; and

f. deflating said balloon cuff;

wherein, when said balloon cuff is deflated, the thickness of the same is reduced such that said balloon cuff is substantially in contact with said tube of said OLT.

35. The method according to claim **32**, additionally comprising a step of initiating ventilation of the patient via the proximal end.

36. The method according to claim **32**, additionally comprising a step of moving a working tool through said OLT.

37. The method according to claim **34**, additionally comprising a step of moving said working tool beyond said mask and into the trachea of said patient.

38. The method according to claim **32**, wherein said integrated tubus and laryngeal mask device further comprises an airway-directing mechanism disposed about one side of said tubus, said method further comprising a step of at least partially maneuvering said airway-directing mechanism whereby said tubus is directed toward the trachea of said patient.

39. The method according to claim **32**, additionally comprising a step of fixedly securing said OLT to said operating position of said tubus.

40. The method according to claim **32**, wherein said OLT is further adapted for guiding said working tool to an operating position to view vocal cords and trachea of said patient.

41. The method according to claim **32**, additionally comprising a step of providing a second balloon disposed about, and in physical contact with, one side of said tubus.

42. The method according to claim **32**, additionally comprising a step of, upon inflation of said inflatable balloon while said tubus is in place, directing at least part of said integrated tubus and laryngeal mask device in the direction of the trachea of said patient.

43. The method according to claim **32**, additionally comprising a step of disposing said second inflatable balloon externally to said tubus.

44. The method according to claim **32**, additionally comprising a step of disposing said second inflatable balloon within said flexible airway.

45. The method according to claim **32**, additionally comprising step of maneuvering and reorienting the distal end of said tubus.

46. The method according to claim **32**, additionally comprising a stopper adapted to fixedly secure said tubus in said operating position of said tubus.

47. The method according to claim **32**, additionally comprising a guide wire substantially accommodated along the length of said OLT; said guide wire is located in an inner canal of said laryngeal mask.

48. The method according to claim **47**, wherein said guide wire is adapted for affixing and stabilizing said laryngeal mask within patient's throat .

49. The method according to claim **32**, wherein said OLT can be easily peeled off by using said guide wire .

50. The method according to claim **32**, wherein said valve is a pilot balloon connected to an inflation lumen extending along the OLT and the tubus.

51. The method according to claim **32**, wherein said lateral movement preventing element is an O-ring.

52. The method according to claim **46**, wherein said O-rings has sizes specified by the outside diameter of the tubus and the cross sectional diameter between said tubus and said OLT.

53. The method according to claim **48**, wherein said O-ring is an elastomeric O-ring for sealing.

54. The method according to claim **32**, wherein said lateral movement preventing element is ring-type balloon.

55. The method according to claim **32**, wherein said lateral movement preventing element is any type of a gasket which has the structure and characteristics to be placed between said tubus and said OLT.

56. The method according to claim **32**, wherein said sealing structure is selected from the group consisting of: a peripheral seal, a radial seal, and any combination thereof.

57. The method according to claim **44**, wherein said stopper is adapted to prevent travel of said tubus lengthwise in said OLT.

58. The method according to claim **44**, wherein said stopper has size, shape and mechanism to reinforce said tubus.

59. The method according to claim **32**, additionally comprising a second valve for controlling inflation and deflation of said second balloon.

60. The method according to claim **32**, wherein said balloon cuff is made of a flexible material.

61. The method according to claim **32**, wherein, when inserting said tubus, said inflation of said balloon cuff to its first state blocks entry of said tubus into the esophagus.

62. The method according to claim **57**, wherein said first state is a state of said integrated tubus and laryngeal mask device which prevents entry of the esophagus into the internal cavity within said mask.

63. The method according to claim **32**, wherein said second balloon is in physical contact with one side of said tubus, whereby, upon inflation of said second balloon while said OLT is in place, at least part of said tubus is directed in a predetermined direction.

64. The method according to claim **32**, wherein said OLT tube has flexible walls integral with said cuff balloon of said OLT; said OLT walls and said cuff balloon walls being substantially in contact when said cuff balloon is deflated.

65. The method according to claim **32**, wherein said balloon is deflated to its second state once inserted to and secured in the correct position, such that it provides no substantial obstruction within the mask.

66. The method according to claim **61**, wherein said second state is a state in which the internal cavity within said mask is substantially open.

67. The method according to claim **32**, wherein said second balloon and balloon cuff are expansible members made of an elastic material.

68. A method of producing an integrated tubus and laryngeal mask device, comprising steps of:

a. providing an outer laryngeal mask tube (OLT) having proximal end and distal portion having: *(i)* a balloon cuff shaped as a laryngeal mask, having at least one inflated configuration and at least one deflated configuration, located in said distal portion; said balloon in a fluid connection with an inflating means, located at said proximal end, and an elongated tube in connection with said balloon cuff (TOLT); *(ii)* an inner tube (tubus); said tubus characterized by a main longitudinal axis; *(iii)* at least one lateral movement preventing element;

b. locating said tubus within said OLT;

c. positioning said lateral movement preventing element circumferentially to said tubus and between said tubus and said OLT;

wherein, said balloon cuff in its deflated configuration is not protruding from said TOLT.

69. The method according to claim **64**, wherein said lateral movement preventing element is adapted both *(i)* to prevent lateral movement of said tubus with respect to said OLT, such that contamination of the environment between said tubus and said OLT is prevented; and *(ii)* to allow longitudinal reciprocating movement of said tubus along said main longitudinal axis with respect to said OLT, in a manner that a seal is provided for the inner volume between said OLT and said tubus.

70. The method according to claim **64**, additionally comprising the step of positioning a stopper at the proximal end of said OLT.

71. The method according to claim **64**, additionally comprising a guide substantially accommodated along the length of said OLT; said guide wire is located in an inner canal of said laryngeal mask.

72. The method according to claim **71**, wherein said guide wire is provided for affixing and stabilizing said laryngeal mask within patient's throat .

73. The method according to claim **64**, wherein said OLT can be easily peeled off by using said guide wire .

74. The method according to claim **64**, wherein said tubus additionally comprises a second inflatable balloon.

75. The method according to claim **64**, additionally comprising the step of sealing the inner volume between said OLT and said tubus with said lateral movement preventing element.

76. The method according to claim **69**, wherein said seal is a peripheral seal.

77. The method according to claim **69**, wherein said seal is a radial seal.

78. The method according to claim **64**, wherein said inflating means is a pilot balloon valve connected to an inflation lumen extending along said OLT and said tubus.

79. The method according to claim **68**, wherein said second balloon is in fluid connection with a second inflating means located at the proximal end of said tubus.

80. The method according to claim **73**, wherein said second inflating means is a pilot balloon valve connected to an inflation lumen extending along said OLT and said tubus.

81. The method according to claim **68**, further wherein said inflating means located at said proximal end is in fluid connection with said lateral movement preventing element.

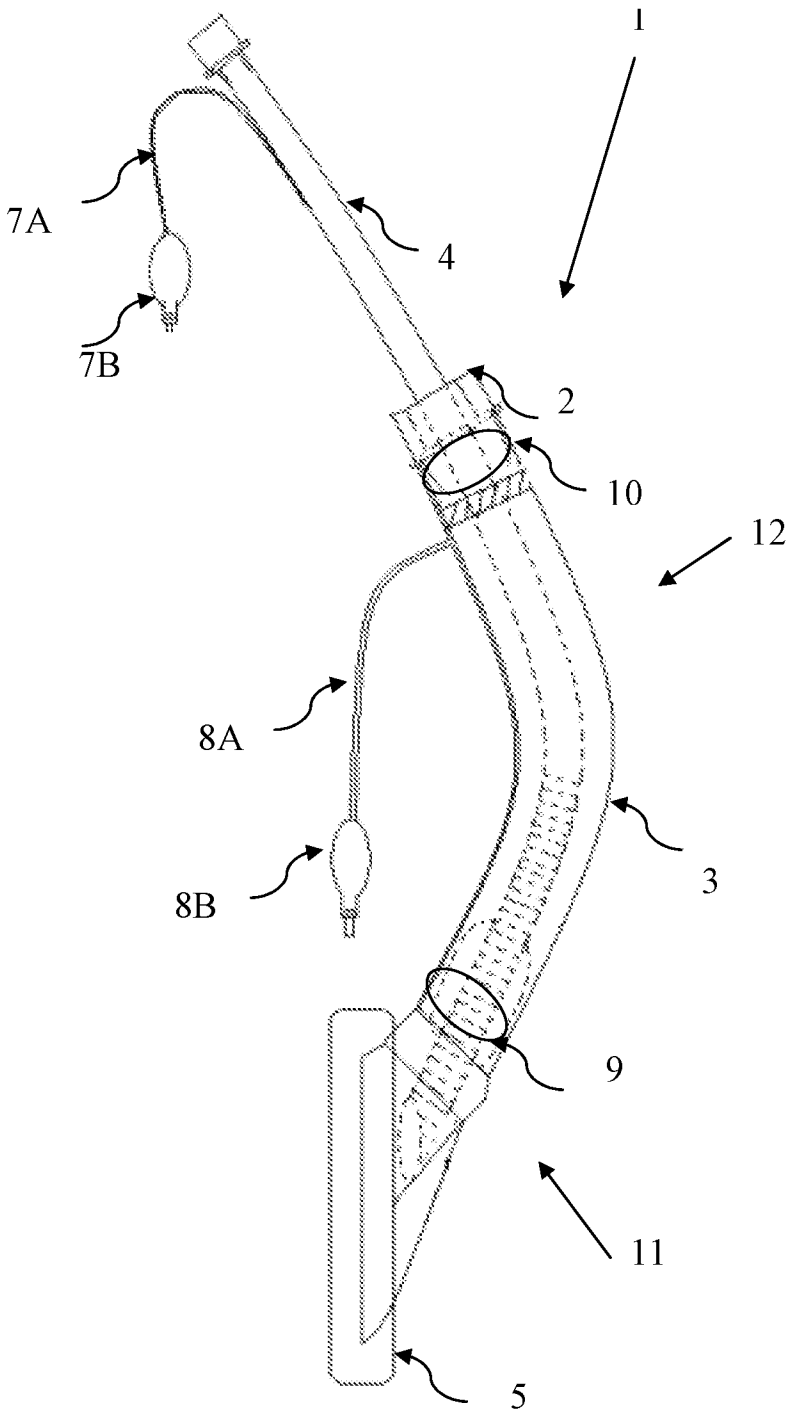

Figure 1

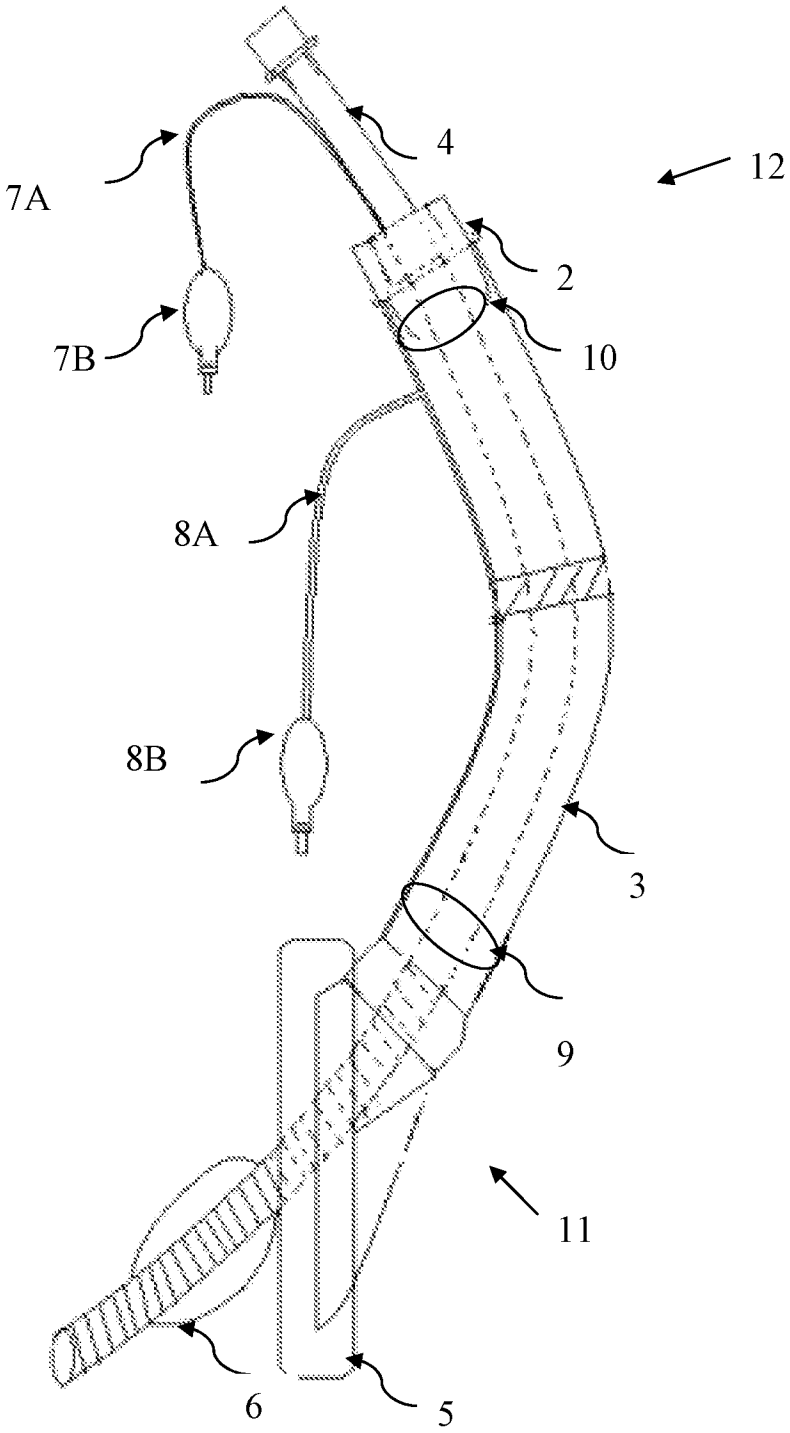

Figure 2

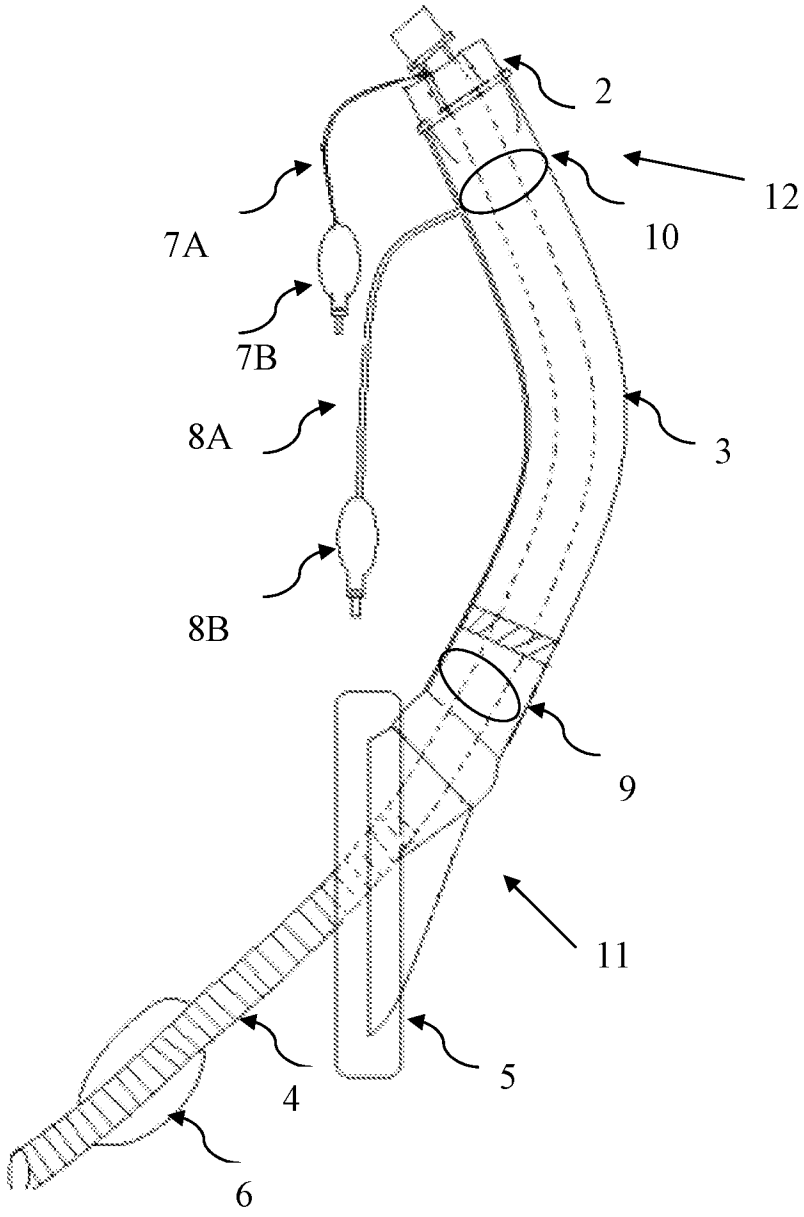

Figure 3

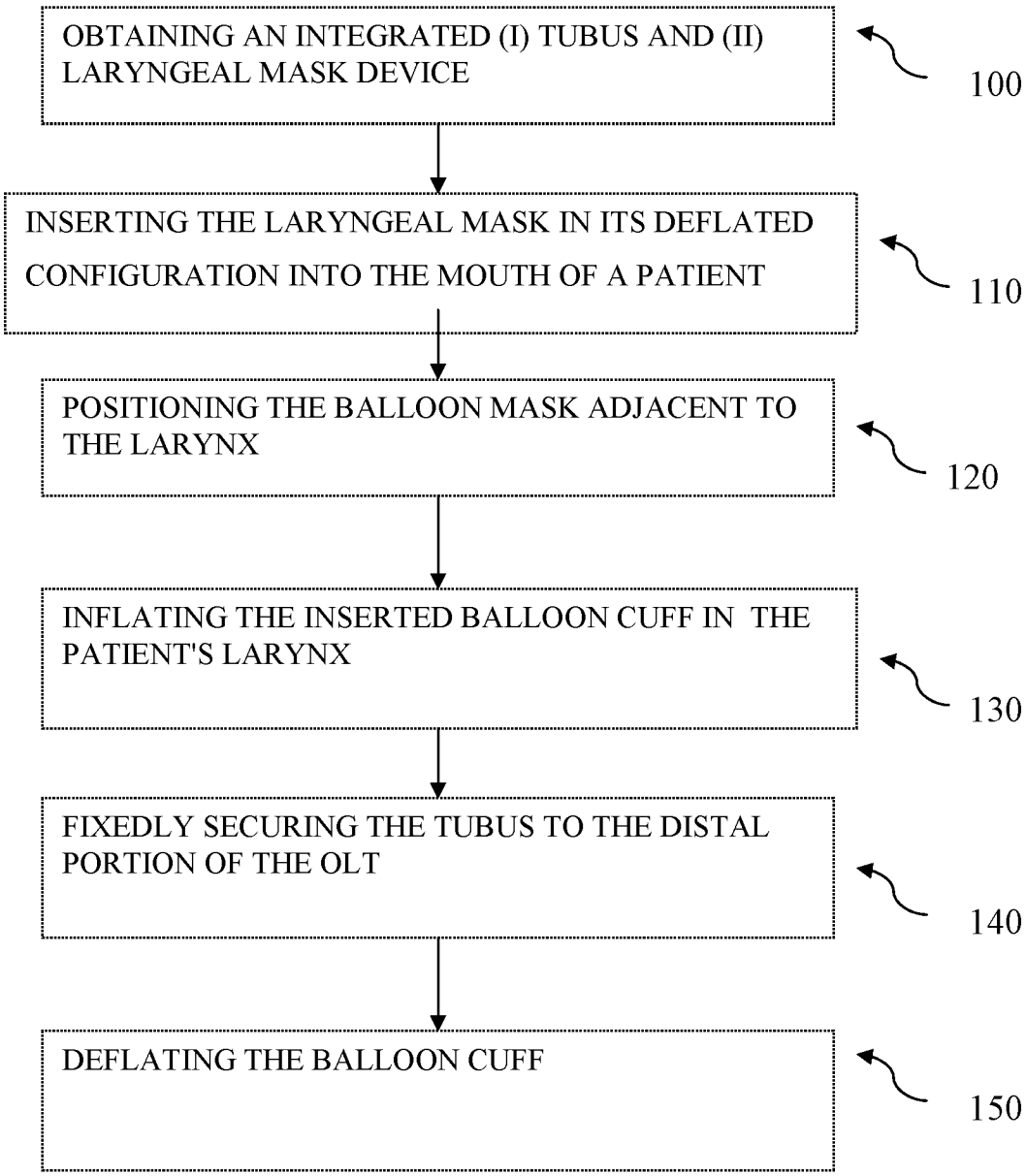
OBTAINING AN INTEGRATED (I) TUBUS AND (II) LARYNGEAL MASK DEVICE
100
INSERTING THE LARYNGEAL MASK IN ITS DEFLATED CONFIGURATION INTO THE MOUTH OF A PATIENT
110
POSITIONING THE BALLOON MASK ADJACENT TO THE LARYNX
120
INFLATING THE INSERTED BALLOON CUFF IN THE PATIENT'S LARYNX
130
FIXEDLY SECURING THE TUBUS TO THE DISTAL PORTION OF THE OLT
140
DEFLATING THE BALLOON CUFF
150

Figure 4

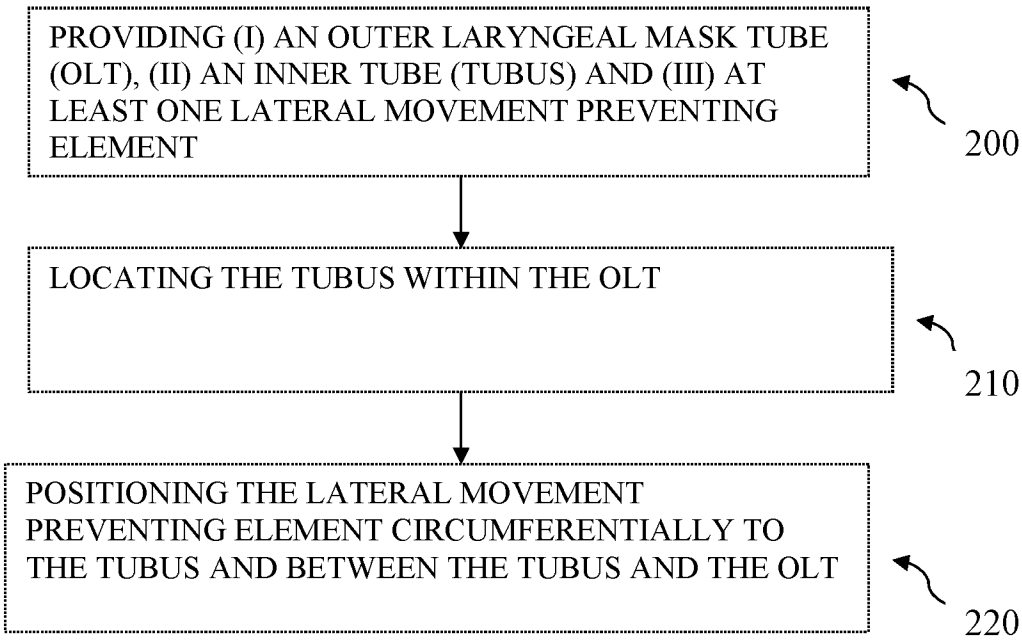
PROVIDING (I) AN OUTER LARYNGEAL MASK TUBE (OLT), (II) AN INNER TUBE (TUBUS) AND (III) AT LEAST ONE LATERAL MOVEMENT PREVENTING ELEMENT
200
LOCATING THE TUBUS WITHIN THE OLT
210
POSITIONING THE LATERAL MOVEMENT PREVENTING ELEMENT CIRCUMFERENTIALLY TO THE TUBUS AND BETWEEN THE TUBUS AND THE OLT
220

Figure 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2013/050879

A. CLASSIFICATION OF SUBJECT MATTER
IPC (2014.01) A61M 16/04

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)
IPC (2014.01) A61M

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)
Databases consulted: Esp@cenet, Google Patents, FamPat database
Search terms used: TUBE, CUFF, LARYNG+, MASK, DEFLAT+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2445655 B SMITHS GROUP PLC 22 Jun 2011 (2011/06/22) the whole document	1-20,22-31,34-37, 39-43,45-81
Y	WO 2008000204 A1 UKSH SCHLESWIG HOLSTEIN; ROEMER THOMAS 03 Jan 2008 (2008/01/03) the whole document especially abstract, figure 1	68
Y	US 2007102001 A1 INDIAN OCEAN MEDICAL INC 10 May 2007 (2007/05/10) paragraphs [0009]; [0015], lines 1-3;[0179]; fig. 12, 16A	1-20,22-31,68-81

☐ 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
"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)
"O" document referring to an oral disclosure, use, exhibition or other means
"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
19 Mar 2014	23 Mar 2014
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Facsimile No. 972-2-5651616	Authorized officer LEVI Moria Telephone No. 972-5651753

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2013/050879

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 21,32,33,38,44
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 21,32,33,38,44 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Said lacks of clarity is prohibiting a proper determination of the subject matter which would be excepted to be claimed, and thereby the examiners unable to establish a meaningful search opinion regarding those claims.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IL2013/050879

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
GB 2445655 B	22 Jun 2011	GB 0700388 D0	14 Feb 2007
		GB 0725157 D0	30 Jan 2008
		GB 2445655 A	16 Jul 2008
		GB 2445655 B	22 Jun 2011
WO 2008000204 A1	03 Jan 2008	DE 102006029182 B3	12 Jul 2007
		WO 2008000204 A1	03 Jan 2008
US 2007102001 A1	10 May 2007	AT 382388 T	15 Jan 2008
		AU 2002321508 B2	03 Apr 2008
		AU 2008202940 A1	31 Jul 2008
		AU 2008202940 B2	19 May 2011
		BR 0212057 A	17 Aug 2004
		BR 0212057 B1	17 Apr 2012
		CA 2458444 A1	06 Mar 2003
		CA 2458444 C	12 Jan 2010
		CA 2683899 A1	06 Mar 2003
		CN 1564698 A	12 Jan 2005
		CN 100376298 C	26 Mar 2008
		CZ 20040267 A3	16 Jun 2004
		DE 60224407 D1	14 Feb 2008
		DE 60224407 T2	18 Dec 2008
		DK 1420843 T3	19 May 2008
		EP 1420843 A1	26 May 2004
		EP 1420843 B1	02 Jan 2008
		EP 1980286 A2	15 Oct 2008
		EP 1980286 A3	29 Oct 2008
		EP 2258431 A1	08 Dec 2010
		EP 2258431 B1	26 Jun 2013
		EP 2258431 B8	07 Aug 2013
		ES 2299594 T3	01 Jun 2008

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IL2013/050879

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
		ES 2433370 T3	10 Dec 2013
		HK 1062540 A1	25 Apr 2008
		HU 0600111 A2	28 Nov 2007
		IL 160467 A	13 Apr 2008
		IL 160467 D0	25 Jul 2004
		JP 2005527246 A	15 Sep 2005
		JP 4249613 B2	02 Apr 2009
		KR 20040048399 A	09 Jun 2004
		KR 100753634 B1	29 Aug 2007
		MX PA04001648 A	22 Nov 2004
		PL 369068 A1	18 Apr 2005
		PL 198866 B1	31 Jul 2008
		RU 2004125596 A	10 Apr 2005
		RU 2299746 C2	27 May 2007
		TW I271201 B	21 Jan 2007
		US 2003037790 A1	27 Feb 2003
		US 7159589 B2	09 Jan 2007
		US 2007102001 A1	10 May 2007
		US 2011203594 A1	25 Aug 2011
		WO 03018094 A1	06 Mar 2003
		ZA 200401322 A	01 Nov 2004