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(54) Title: ARTIFICIAL AIRWAY DEVICE

(57) **Abstract:** The invention relates to an artificial airway device (1) to facilitate lung ventilation of a patient, comprising an airway tube (2) and a mask (3) cannulated at one end of the airway tube, the mask (3) having a distal end (4) and a proximal end (5) and a peripheral formation (6) capable of conforming to, and of fitting within, the actual and potential space behind the larynx of the patient so as to form a seal around the circumference of the laryngeal inlet, the peripheral formation (6) surrounding a hollow interior space or lumen (7) of the mask (3) and the airway tube (2) opening into the lumen (7) of the mask, the mask having a conduit (8) for receiving, in use, oesophageal matter, an outer, in use, surface of the peripheral formation (6) defining a channel (10) for use in facilitating drainage of oesophageal matter.

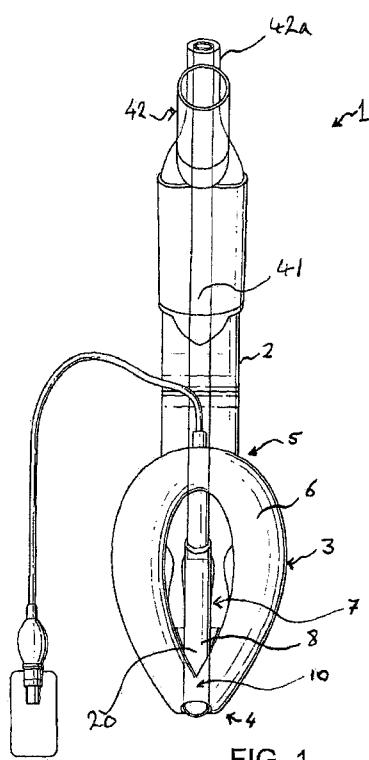


FIG. 1



SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, **Published:**
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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

ARTIFICIAL AIRWAY DEVICE

The present invention relates to an artificial airway device.

5

Artificial airway devices such as the laryngeal mask airway device are well known devices useful for establishing airways in unconscious patients. In its most basic form a laryngeal mask airway device consists of an airway tube and a mask carried at one end of the airway tube, the mask having a peripheral formation often known as a "cuff" which is capable of

10 conforming to and of fitting within, the actual and potential space behind the larynx of the patient so as to form a seal around the laryngeal inlet. The cuff can be inflatable, and in most variants it surrounds a hollow interior space or lumen of the mask, the at least one airway tube opening into the lumen. U.S. Patent No. 4,509,514 is one of the many publications that describe laryngeal mask airway devices such as this. Such devices have been in use for many
15 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 trachea. Once so positioned, the balloon is inflated so as to form a
20 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).

25 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
30 manipulation of the patient's head, neck and jaw. Further, the laryngeal mask airway device provides 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.

5

U.S. Patent Nos. 5,303,697 and 6,079,409 describe examples of prior art devices that may be referred to as "intubating laryngeal mask airway devices." The intubating device has the added advantage that it 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 10 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 15 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. Furthermore, these devices permit single-handed insertion from any user position without moving the head and neck of the patient from a neutral position, and can also be put in place without inserting fingers in the patient's mouth. 20 Finally, it is believed that they are unique in being devices which are airway devices in their own right, enabling ventilatory control and patient oxygenation to be continuous during intubation attempts, thereby lessening the likelihood of desaturation.

Artificial airway devices of the character indicated are exemplified by the disclosures of US 25 Pat. No. 4,509,514; U.S. Pat. No. 5,249, 571; U.S. Pat No. 5,282,464; U.S. Pat. No. 5,297,547; U.S. Pat. No. 5,303,697; and by the disclosure of UK Patent 2,205,499.

Furthermore, devices with additional provision for gastric-discharge drainage are exemplified by EP 0 794 807; U.S. Pat. No. 4,995,388 (Figs. 7 to 10); U.S. Pat. No. 5,241,956; and U.S. 30 Pat. No. 5,355,879 and commonly known as gastro-laryngeal masks. These masks make provision for airway assurance to the patient who is at risk from vomiting or regurgitation of stomach contents whilst unconscious. From a reading of these prior art documents it will be

appreciated that gastro-laryngeal masks present numerous and often conflicting requirements of design and manufacture to achieve designs that do not sacrifice any of the benefits of the more simpler designs described above.

5 Thus, in general, laryngeal mask airway devices aim to provide an airway tube of such cross-section as to assure more than ample ventilation of the lungs. Designs with provision for gastric drainage have been characterized by relatively complex internal connections and cross-sections calculated to serve in difficult situations where substantial solids could be present in a gastric discharge. As a result, the provision of a gastric discharge opening at the

10 distal end of the mask applicable for direct service of the hypopharynx has resulted in a tendency for such masks to become bulky and unduly stiff, thus making for difficulty in properly inserting the mask. Undue bulk and stiffness run contrary to the requirement for distal flexibility for tracking the posterior curvature of the patient's anatomy on insertion, in such manner as to reliably avoid traumatic encounter. Moreover, manufacturing is made much

15 more difficult and costly and the risks of device failure may be increased.

Problems such as these can be especially acute in devices formed from relatively rigid materials, like PVC, as opposed to the more traditional Liquid Silicon Rubber (LSR). In general, devices formed from materials such as PVC are attractive because they are cheaper to

20 make, and can be offered economically as "single-use" devices. However, there are material differences in PVC and LSR adhesives, such as increased durometer hardness as compared to LSR, which affect how devices perform in use. For example, it has been observed that for a given volume of air, an LSR cuff will expand to a larger size than a comparable PVC cuff. This superior elasticity allows the LSR cuff to provide an anatomically superior seal with

25 reduced mucosal pressure. To close the performance gap, the PVC cuff must be of reduced wall thickness. However, a PVC cuff of reduced wall thickness, deflated and prepared for insertion, will suffer from poor flexural response as the transfer of insertion force through the airway tube to cuff distal tip cannot be adequately absorbed. The cuff assembly must deflate to a thickness that preserves flexural performance i.e. resists epiglottic downfolding, but

30 inflate so that a cuff wall thickness of less than or equal to 0.4mm creates a satisfactory seal. And where mask backplates are formed from PVC, as well as cuffs, the fact that the increased durometer hardness of PVC is inversely proportional to flexural performance (hysteresis)

means that the flexural performance of the device in terms of reaction, response and recovery on deformation is inferior to a comparable LSR device.

The above described problems are particularly acute in devices which incorporate an
5 oesophageal drain. As mentioned above, in any such device regardless of the material from
which it is formed, adding an oesophageal drain in itself adds greatly to complexity of
manufacture and can also affect the performance of devices, in terms of ease of insertion, seal
formation and prevention of insufflation. These problems can be exacerbated still further if
PVC or similarly performing materials are used. For example, the skilled worker will
10 appreciate that in terms of manufacture, the need to provide a drain tube which is sealed from
the airway, and which must pass through the inflatable cuff poses a particularly difficult
problem. In terms of effects on functionality, the provision of a drain tube can cause
unacceptable stiffening of the mask tip area and occlusion/restriction of the airway passage.

15 It is an object of the present invention to seek to mitigate problems such as these.

According to a first aspect of the invention there is provided an artificial airway device to
facilitate lung ventilation of a patient, comprising at least one airway tube and a mask carried
at one end of the at least one airway tube, the mask having a distal end and a proximal end
20 and a peripheral formation capable of forming a seal around the circumference of the
laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen of the
mask and the at least one airway tube opening into the lumen of the mask, the mask having a
conduit for receiving, in use, oesophageal matter, an outer, in use, surface of the peripheral
formation defining a channel for use in facilitating drainage of oesophageal matter. In this
25 way, the invention provides a device that is simpler and easier to manufacture because the
requirement for the conduit to pass through the peripheral formation is avoided.

The peripheral formation may be inflatable, such as for example an inflatable cuff. The
channel may be for example a C- or U-shaped channel formed in and/or by the material from
30 which the peripheral formation is formed, such as PVC, which is thermoformable. The
channel will preferably extend from the distal end of the mask towards the proximal end of
the mask and may connect with a drainage tube of the mask, or of the airway tube. The

channel may be closed by an extension of the drainage tube of the mask or of the airway tube, which extension may extend to a point short of the distal end of the channel and terminate in a substantially smooth and rounded end. It has been found that such an end formation helps avoid the possibility of trauma during insertion of the device.

5

In an alternative embodiment, the channel may perform its function of facilitating drainage of oesophageal matter by defining a path through which a drainage tube of the mask and/or the airway tube can extend.

- 10 10 It is preferred that the mask describes a substantially convex curve, from the proximal to distal end. It is further preferred that the mask body comprises a plate, the plate having a dorsal side and a ventral side, the dorsal side being substantially smooth and having a convex curvature across its width. It is also preferred that the dorsal surface of the airway tube corresponds in curvature to the curvature across the width of the plate. All of these expedients assist in making insertion of the mask easier.
- 15

The airway tube preferably comprises a relatively more rigid material than the mask body. Both the airway tube and the mask body preferably comprise a plastics material.

- 20 20 The airway tube may be adapted to include a relatively softer wall portion adjacent a point that in use will be adjacent the patient's teeth. It is preferred that the airway tube includes dorsal and ventral surfaces and that the relatively softer wall portion is disposed at one or both of the dorsal or ventral surfaces. The relatively softer portion may comprise a relatively softer material, or may comprise an unsupported portion of the airway tube. It is preferred that the airway tube includes a bite-block that supports the airway tube against biting by the patient and that the relatively softer portion is provided by a cutaway of the bite block. For the avoidance of doubt, the airway device may or may not have means for removal of oesophageal material.
- 25
- 30 30 The invention will further be described by way of example and with reference to the following drawings, in which,

Figure 1 is an underplan, or ventral view of a device according to the invention;

Figure 2 is an exploded view of a part of the device of Figure 1;

5 Figure 3 is a perspective ventral view of the mask of the device of Figure 1;

Figure 4 is a front end view of the mask shown in Figure 3 in a first position;

Figure 5 is a front end view of the mask shown in Figure 3 in a second position;

10

Figure 6 is a side view of the device of Figure 1; and

Figure 7 is a plan, or dorsal view of the device of Figure 1.

15 Referring now to the drawings, there is illustrated an artificial airway device 1 to facilitate lung ventilation of a patient, comprising at least one airway tube 2 and a mask 3 carried at one end of the at least one airway tube, the mask 3 having a distal end 4 and a proximal end 5 and a peripheral formation 6 capable of conforming to, and of fitting within, the actual and potential space behind the larynx of the patient so as to form a seal around the circumference 20 of the laryngeal inlet, the peripheral formation 6 surrounding a hollow interior space or lumen 7 of the mask 3 and the at least one airway tube 2 opening into the lumen 7 of the mask, the mask having a conduit 8 for receiving, in use, oesophageal matter, an outer, in use, surface 9 of the peripheral formation 6 defining a channel 10 for use in facilitating drainage of oesophageal matter.

25

As can be seen from the drawings, the device 1, in terms of overall appearance is somewhat similar to prior art devices, in that it consists of the basic parts which make up most if not all laryngeal mask airway devices, i.e. an airway tube 2 and mask 3. The mask 3 includes two components, a body part 11 often referred to as a backplate (shown in Figures 6 and 7), and a 30 peripheral formation 6 which here takes the form of an inflatable cuff with an inflation line 12.

For the purposes of description it is convenient to assign reference names to areas of the device 1 (as opposed to its constituent parts) and accordingly with reference to Figures 6 and 7, the device 1 has a dorsal side 14, a ventral side 15, a proximal end 16 (in a sense that this is the end nearest the user rather than the patient) a distal end 17 and right and left sides 18 and 5 19.

Referring firstly to the airway tube 2, in the illustrated embodiment the tube 2 comprises a relatively rigid PVC material such as a shore 90A Colorite PVC moulded into an appropriately anatomically shaped curve. The tube 2 has some flexibility such that if it is bent 10 it will return to its original shape. Although it is resiliently deformable in this way, it is also sufficiently rigid to enable it to assist in insertion of the device 1 into a patient, acting as a handle and guide for positioning the mask. The airway tube 2 does not have a circular cross-section as in many prior devices, but instead is compressed in the dorsal/ventral direction which assists in correct insertion of the device 1, helps prevent kinking, and assists in 15 comfortable positioning for the patient as the shape generally mimics the shape of the natural airway. In this embodiment each side 18, 19 of the airway tube 2 also includes a groove or channel 20 extending for most of the tube's length from the proximal to distal ends. These grooves 20 further assist in preventing crushing or kinking of the airway tube 2. Internally the grooves 20 form ridges along the inner surfaces of the sides 18 and 19, but this is not essential to 20 their operation.

A further feature of the airway tube 2 is oesophageal drain tube 41. This drain tube 41 is located within airway tube 2, extending centrally through it from the proximal end to the distal end, and in this embodiment it is disposed in contact with the inner surface of the dorsal 25 wall 2b of the airway tube 2, and bounded on each side by raised, smooth walls (not shown) which form a shallow channel through which it runs. At the proximal end of the airway tube 2, the drain tube 41 exits the airway tube 2 via branch 42a of a bifurcated connector 42, to which a suction line may be attached.

30 Bifurcated connector 42 also allows for connection of the airway tube to a gas supply via branch 42b. Here it is formed from a relatively rigid plastics material (when compared with the airway tube 2) to enable easy connection of air lines and suction. Referring to Figure 2,

connector 42 comprises a hollow somewhat flattened, conical connector body 43 defining an atrium having branches 42a and 42b extending from its narrower, proximal end. Conical body 43 includes a circumferential flange 42c from which extends tab 42d in a direction generally normal to the longitudinal axis of the connector. An insert section 44 extends longitudinally

5 from the distal end of the conical body 43. The insert section 44 can be described as a tube, flattened in the dorsal to ventral direction and having two sections of wall removed leaving gaps 44e and "arms" 44a. The insert section 44 corresponds in shape and dimension with the internal shape of the proximal end of the airway tube 2 such that it fits inside it, with arms 44a providing support and rigidity to the sides of the airway tube. As a result of the removed wall
10 sections 44e the support for the parts of the airway tube 2 adjacent the removed sections is reduced. A sleeve 45 of a soft and compliant material is bonded in placed around the outside of the airway tube 2, covering the area into which the insert section 44 locates, and the thickness of the airway tube wall at this point can be reduced to accommodate this such that the overall thickness at this point 46 is not increased. Thus, it will be appreciated that this
15 configuration provides a bite block that not only supports the airway tube 2 at a point where the patient's teeth are normally located when the device is in use, but also guards against damage to the teeth by virtue of the less rigid parts. It will be appreciated that this form of connector can also be applied to airway devices that do not include an oesophageal drain.

20 Turning now to the mask 3, the mask 3 consists of two parts, a body part 11 often referred to as a back plate, and a peripheral cuff 6.

The back plate 11 is formed by moulding from a shore 50A Vythene PVC + PU. This material is substantially softer and more deformable than the material of airway tube 2. The
25 back plate 11 comprises a generally oval moulding when viewed from the dorsal or ventral directions, having a smooth dorsal surface 24, and a formed ventral surface 24a (Figure 5). The dorsal surface 24 has a convex curvature from one side to the other, corresponding to the curvature of the dorsal surface of the airway tube 2, and longitudinally, the dorsal surface 24 is also curved, having a curvature beginning at the joining portion 24b and extending with
30 constant rate of curvature toward the distal tip. As a result the tip is ventrally biased relative to the distal end of the airway tube, in the assembled device 1, the extent of displacement of the distal tip being approximately 20mm or 10 degrees, in order to produce a curvature in the

mask that is suited to the anatomy of the patient. On insertion, this displacement of the tip assists the mask in "turning the corner" in the insertion path.

Backplate 11 includes an integrally moulded cylindrical drain tube 20 that extends from its 5 proximal to distal ends. At the proximal end, the drain tube 11 is dimensioned such that it can be joined to the drain tube of the airway tube. At its distal end, the wall of the drain tube 20 has a cut away portion 21, and a smooth, turned over edge.

The second part of the mask 3 is the peripheral cuff 6. The cuff 6 is in this embodiment blow 10 moulded PVC and takes the form of a generally elliptical inflatable ring, a relatively deeper proximal end 37 with an inflation port 38 and a relatively shallower distal end tapering to a "wedge" profile 39. At the distal end the cuff is formed with a channel 22 in its dorsal surface, the channel being of an open C shape that runs in a proximal to distal direction to the tip of the cuff. The cuff 6 is integrally formed in one piece. The wedge profile is provided such that 15 the ratio of dorsal to ventral side surface areas favours the dorsal side. Thus, when deflated the distal end of the cuff 6 will curl with bias from dorsal to ventral side.

The cuff 6 is bonded to the backplate 11 such that the cut away section of the drain tube 20 extends over the channel 22 in the dorsal surface of the backplate 11, thereby forming a tube, 20 part of the wall of which is formed by the backplate and part by the cuff 6. The tube terminates at or just before the distal extremity of the cuff, the smooth edge flaring to some extent in a dorsal direction.

In use, the deflated device 1 is inserted into a patient in the usual manner with devices of this 25 type. As noted above, the relative rigidity of the airway tube 2 allows a user to grip it and use it to guide the device 1 into the patient, whilst the relatively softer, more compliant material of the back plate means that the mask will more readily deform to negotiate the insertion path without causing damage to the anatomy, and will return to its optimum shape to ensure that a good seal is achieved at the furthest extent of insertion. The ventral displacement of the distal 30 tip relative to the join between the back plate 11 and airway tube 2 further enhances ease of insertion, because the distal tip is thereby presented at the optimum angle to negotiate the "bend" in the insertion path. In devices formed from relatively rigid materials such as PVC, as

opposed to the often used LSR these features are particularly important in easing insertion and providing for an enhanced seal. It will be appreciated that, as the oesophageal drain tube does not pass through the interior of the cuff as with prior designs, but instead resides in the channel formed on its surface the device is both easier to manufacture and more resistant to
5 failure as the integrity of the cuff is maintained.

Claims

1. An artificial airway device to facilitate lung ventilation of a patient, comprising at least one airway tube and a mask carried at one end of the airway tube, the mask having a distal end and a proximal end and a peripheral formation capable of forming a seal around the circumference of the laryngeal inlet, the peripheral formation surrounding a hollow interior space or lumen of the mask and the at least one airway tube opening into the lumen of the mask, the mask having a conduit for receiving, in use, oesophageal matter, characterised in that an outer, in use, surface of the peripheral formation defines a channel for use in facilitating drainage of oesophageal matter.
2. A device according to claim 1, wherein the peripheral formation comprises an inflatable cuff.
3. A device according to claim 1 or claim 2, the channel comprising a C- or U-shaped channel formed in and/or by the material from which the peripheral formation is formed.
4. A device according to claim 3, wherein the peripheral formation comprises PVC.
5. A device according to any of claims 1 to 4, wherein the channel extends from the distal end of the mask towards the proximal end of the mask and is in fluid communication with a drainage tube of the mask.
6. A device according to any of claims 1 to 4 wherein the channel extends from the distal end of the mask towards the proximal end of the mask and is in fluid communication with a drainage tube of the airway tube.
7. A device according to claim 5 or claim 6, wherein the channel is closed over by an extension of the drainage tube of the mask or of the airway tube, which extension extends therefrom to a point short of the distal end of the channel and terminates in a substantially smooth and rounded end.

8. A device according to claim 1, wherein the channel facilitates drainage of oesophageal matter by defining a path through which a drainage tube of the mask and/or the airway tube can extend.
9. A device according to any preceding claim, wherein the mask describes a substantially convex curve, from the proximal to distal end.
10. A device according to any preceding claim, wherein the mask body comprises a plate, the plate having a dorsal side and a ventral side, the dorsal side being substantially smooth and having a convex curvature across its width.
11. A device according to claim 10, wherein the dorsal surface of the airway tube corresponds in curvature to the curvature across the width of the plate.
12. A device according to any preceding claim, wherein the airway tube comprises a relatively more rigid material than the mask body.
13. A device according to any preceding claim, the airway tube being adapted to include a relatively softer wall portion adjacent a point that in use will be adjacent the patient's teeth.
14. A device according to claim 13, the airway tube including dorsal and ventral surfaces and that the relatively softer wall portion being disposed at one or both of the dorsal or ventral surfaces.
15. A device according to claim 14, the relatively softer portion comprising a relatively softer material.
16. A device according to claim 14, the relatively softer portion comprising an unsupported portion of the airway tube.
17. A device according to any of claims 13 to 16, the airway tube including a bite-block that supports the airway tube against biting by the patient, the relatively softer portion being provided by a cutaway of the bite block.

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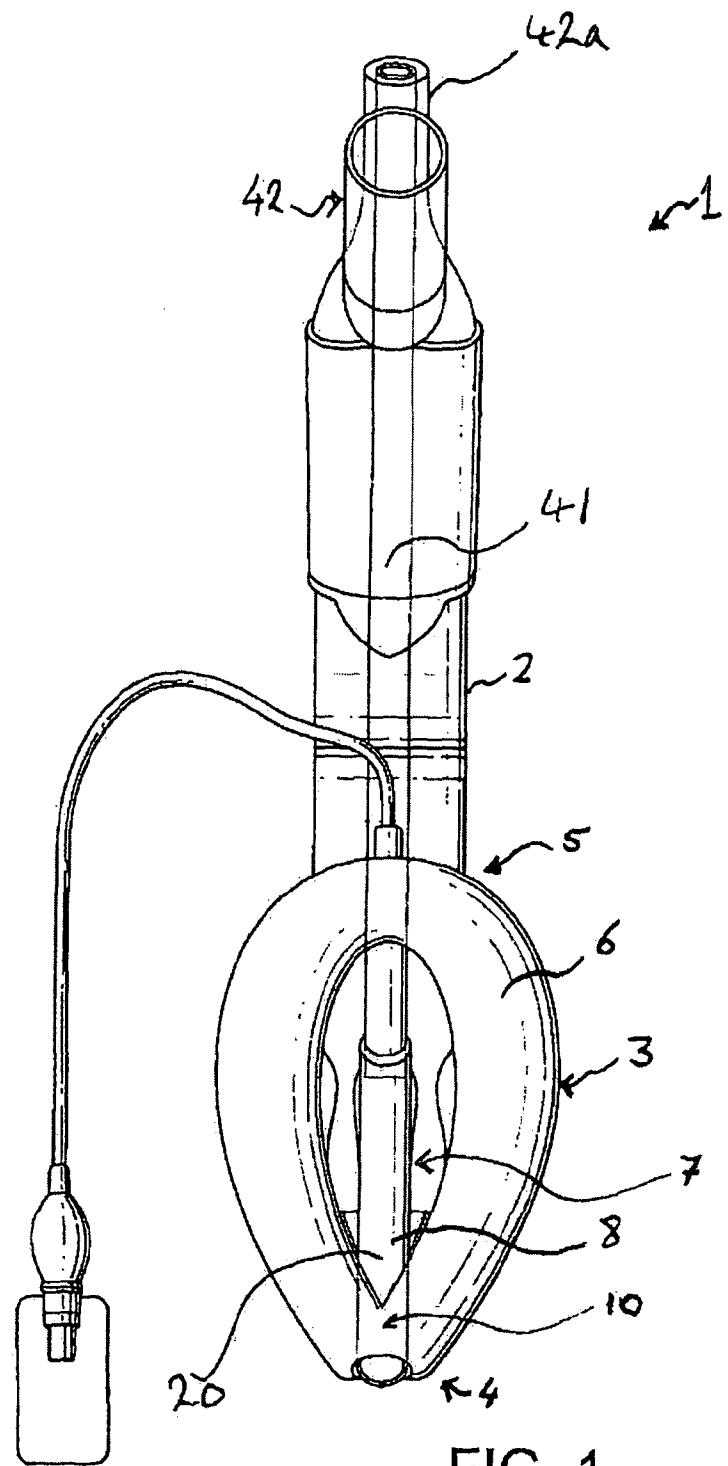


FIG. 1

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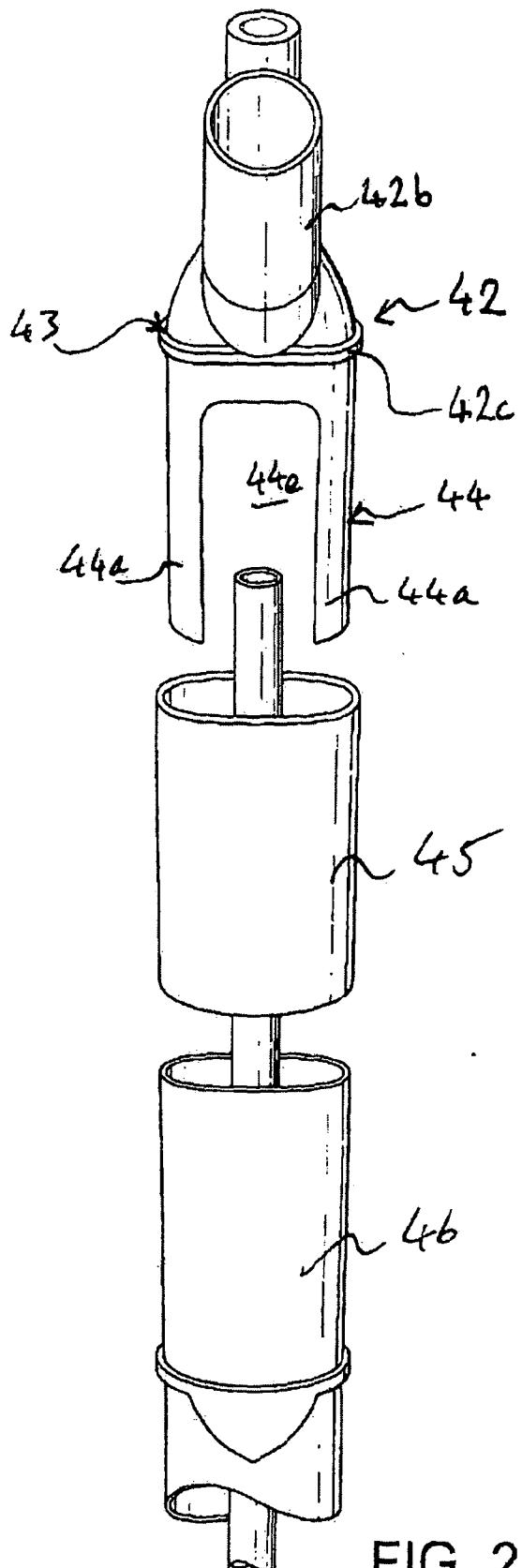


FIG. 2

3 / 7

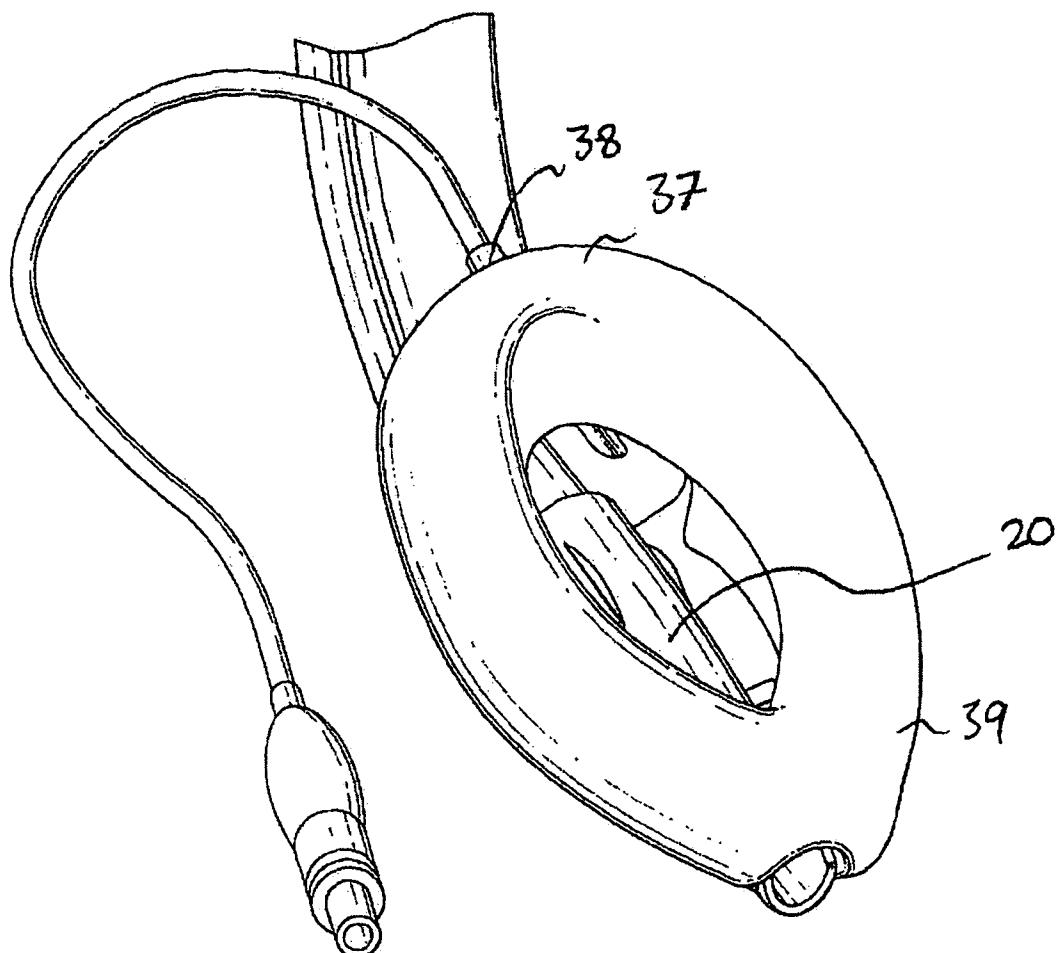


FIG. 3

4 / 7

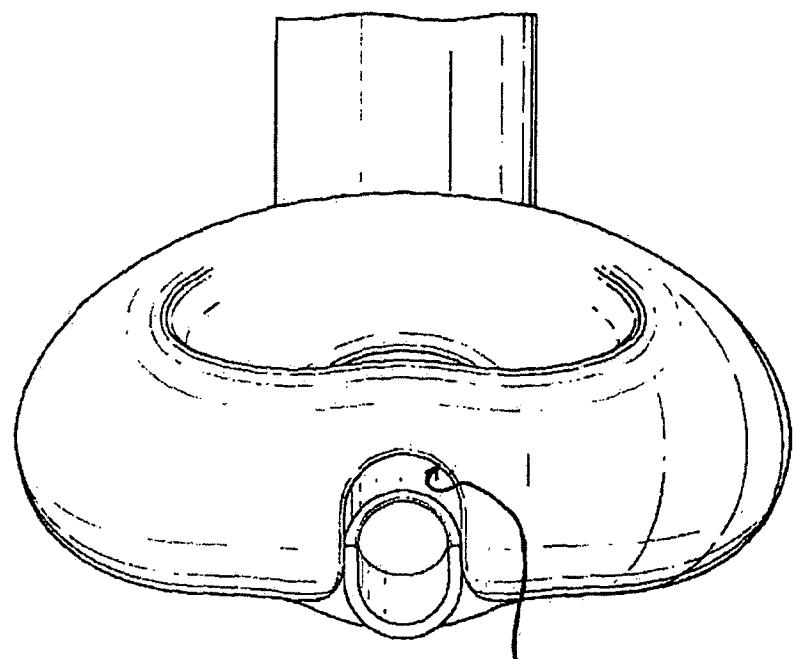


FIG. 4 22

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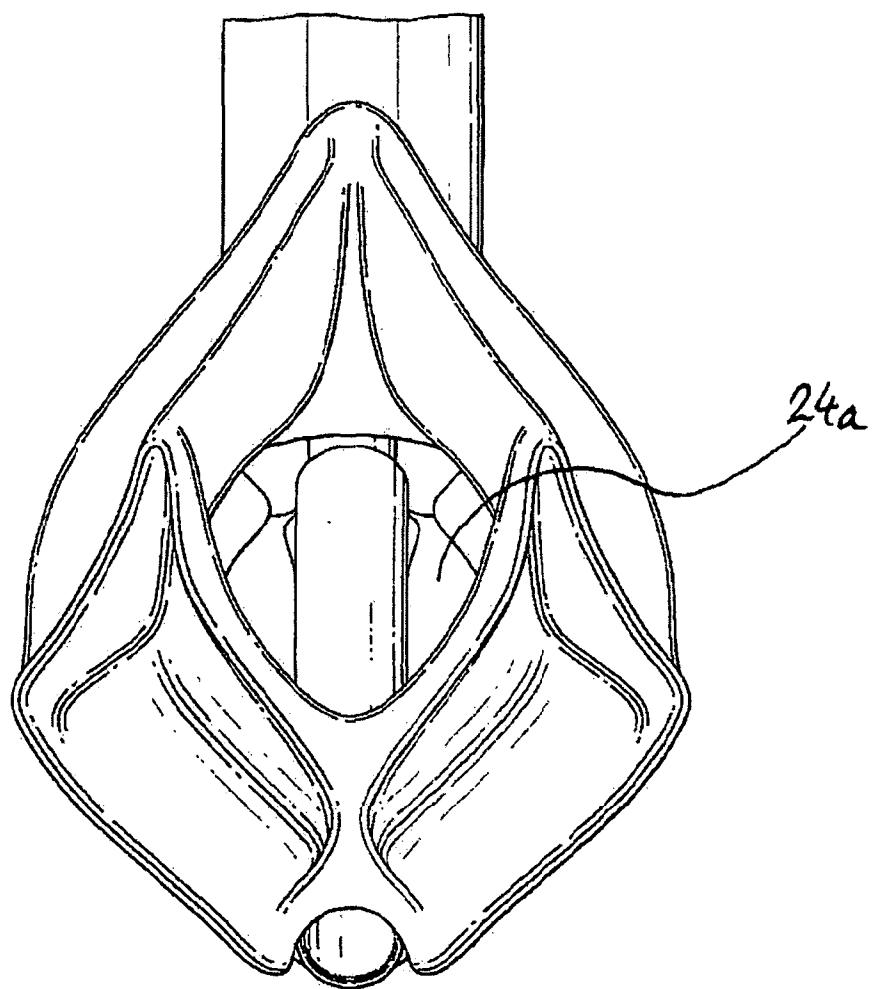


FIG. 5

6/7

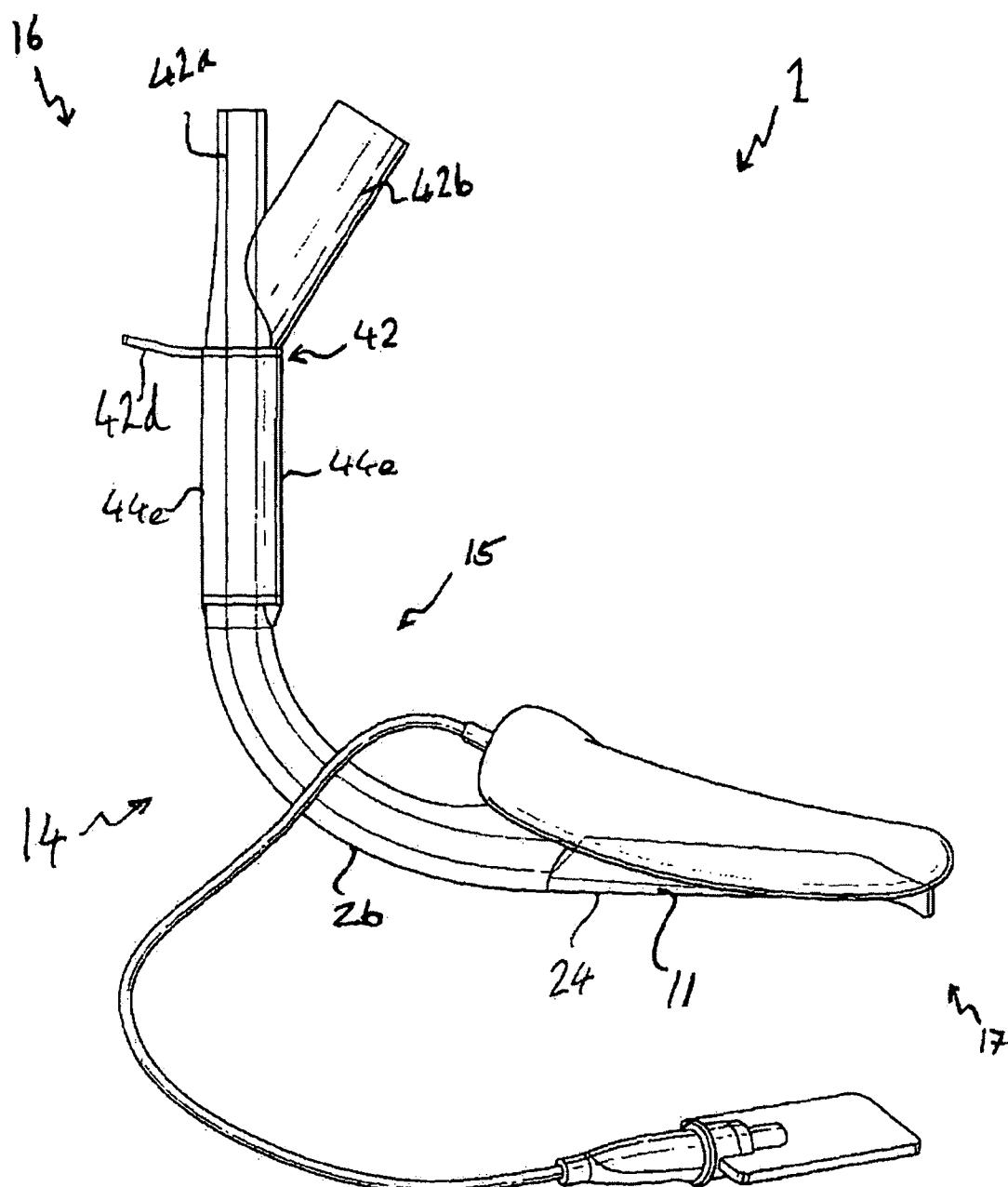


FIG. 6

7 / 7

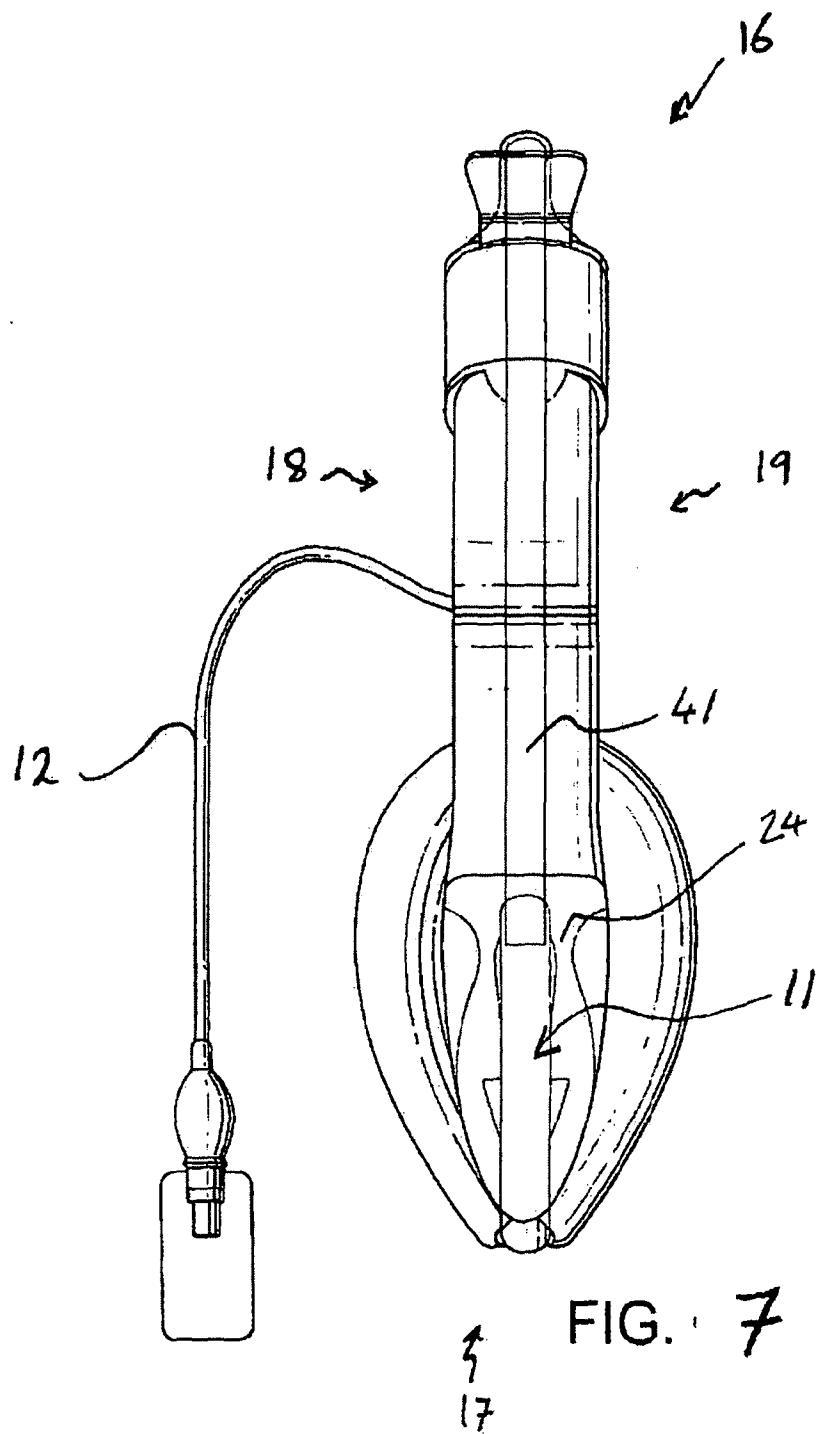


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2011/001420

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
ADD.

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)
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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94/02191 A1 (BRAIN ARCHIBALD IAN JEREMY [GB]) 3 February 1994 (1994-02-03) The whole document, especially Fig. 2 -----	1-17
X	EP 1 938 855 A1 (CHANG TI-LI [TW]) 2 July 2008 (2008-07-02) The whole document, especially Fig. 4 -----	1,3-17
X	WO 2009/026628 A1 (BASKA MEENAKSHI [AU]; BASKA KANAG [AU]) 5 March 2009 (2009-03-05) The whole document, especially Fig. 34, 35, 40-42 and page 10, lines 10-13 -----	1-17
X	GB 2 404 863 A (NASIR MUHAMMED ASLAM [GB]) 16 February 2005 (2005-02-16) The whole document, especially page 11, lines 12-21 ----- -/-	1-17

Further documents are listed in the continuation of Box C.

See patent family annex.

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