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Callaghan et al.

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[54] **LARYNGEAL MASK ASSEMBLY AND METHOD FOR REMOVING SAME**

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[73] Assignee: **The Laryngeal Mask Company Ltd.**, Nicosia, Cyprus

[21] Appl. No.: **644,213**

[22] Filed: **May 10, 1996**

Related U.S. Patent Documents

Reissue of:

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Issued: **Dec. 26, 1995**
Appl. No.: **378,775**
Filed: **Jan. 26, 1995**

[51] **Int. Cl.**[6] **A61M 16/00**; A61M 19/00

[52] **U.S. Cl.** **128/207.15**; 128/200.23; 604/76

[58] **Field of Search** 128/207.14, 207.19, 128/206.26, 207.16, 200.26; 604/96–103, 174

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Assistant Examiner—Eric P. Raciti
Attorney, Agent, or Firm—Hopgood, Calimafde, Kalil & Judlowe

[57] **ABSTRACT**

A laryngeal mask assembly (**10**) includes an artificial airway tube (**14**) and an inflatable mask (**26**). The mask (**26**) is forced into the mouth (**20**) of a patient (**12**) to an operating position adjacent the larynx (**21**). A scoping instrument (**22**) is sent through the artificial airway tube (**14**) and the inflatable mask (**26**) to locate the vocal cords (**23**) and trachea (**35**). The artificial airway tube (**14**) and inflatable mask (**26**) are removed, keeping the scoping instrument (**22**) in a position within the trachea (**35**) whereafter the laryngeal mask assembly (**10**) is removed by peeling it off the scoping instrument (**22**) using the slit (**34**) creating by the overlapping edges (**36**, **38**).

11 Claims, 2 Drawing Sheets

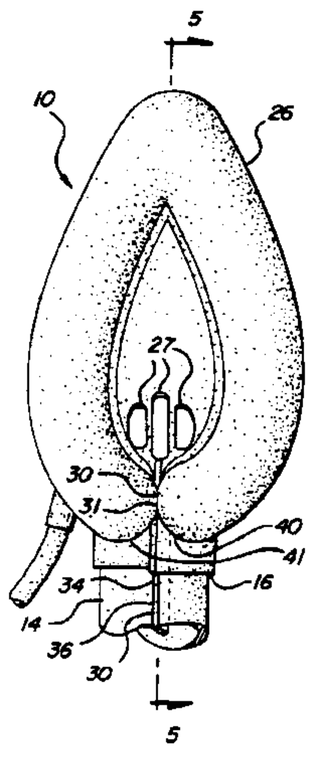


FIG-1

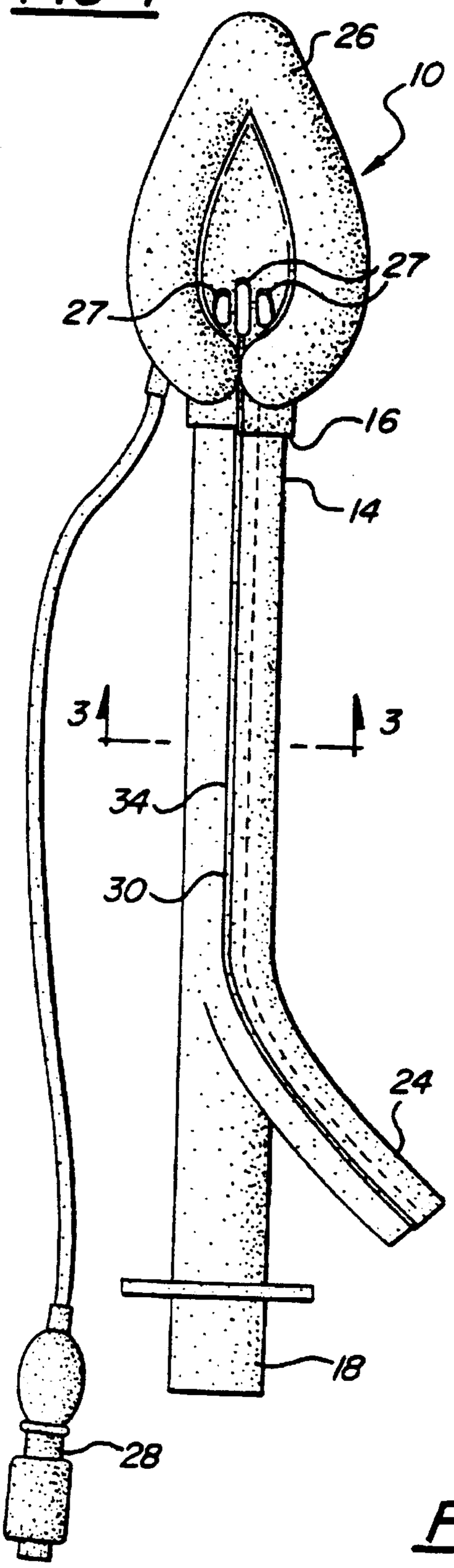
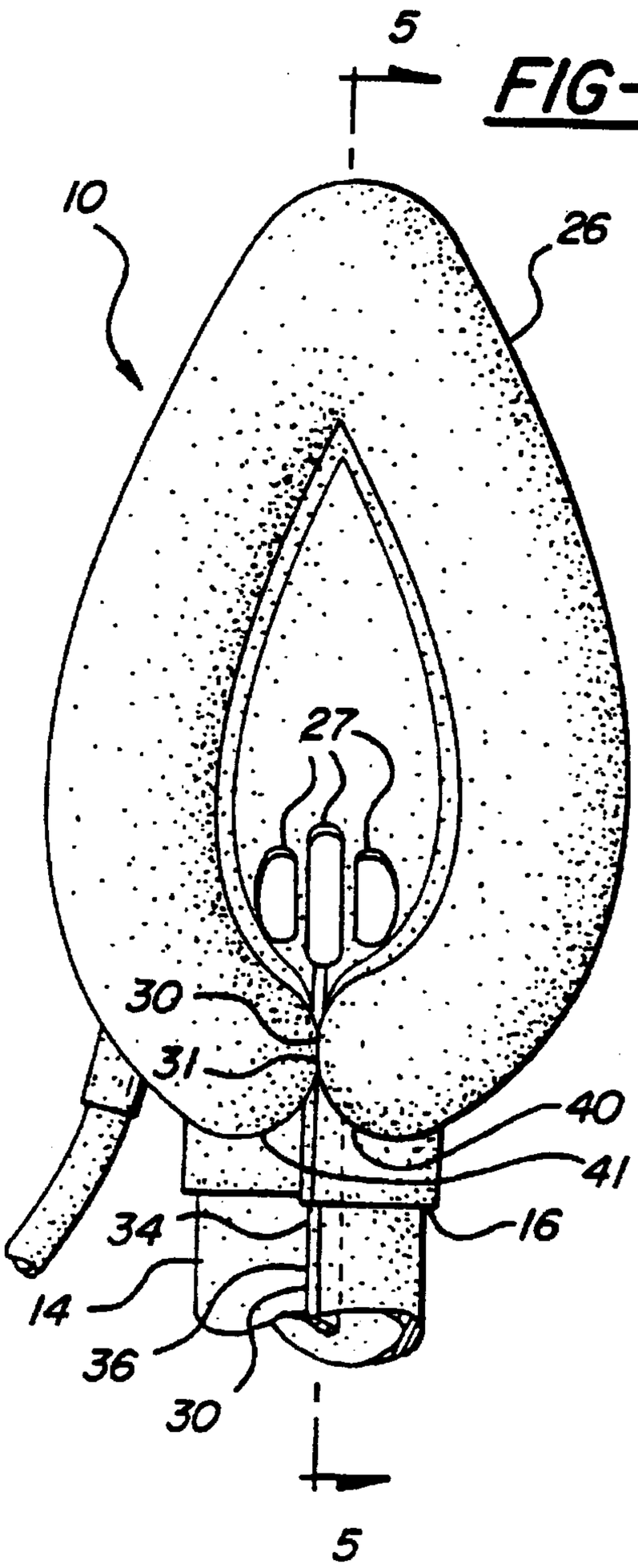


FIG-2



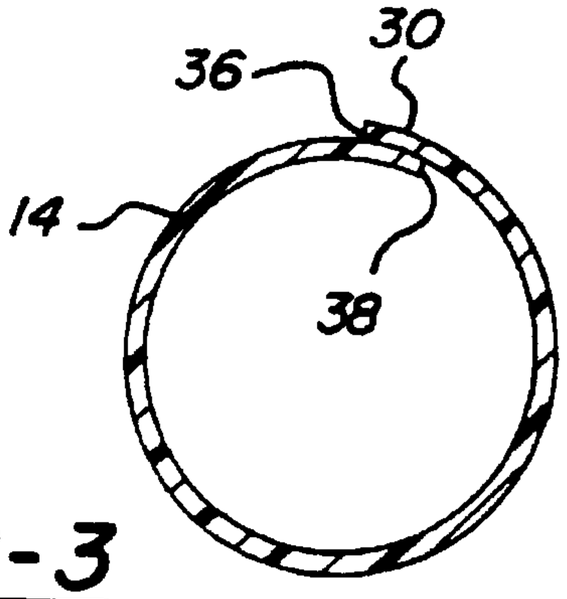


FIG-3

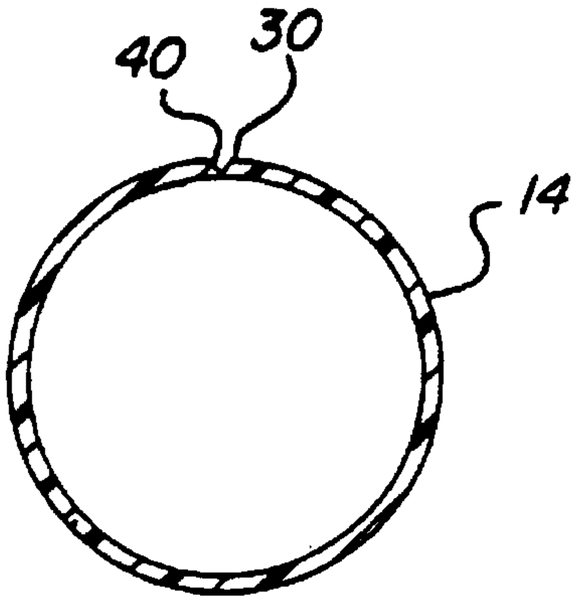


FIG-4

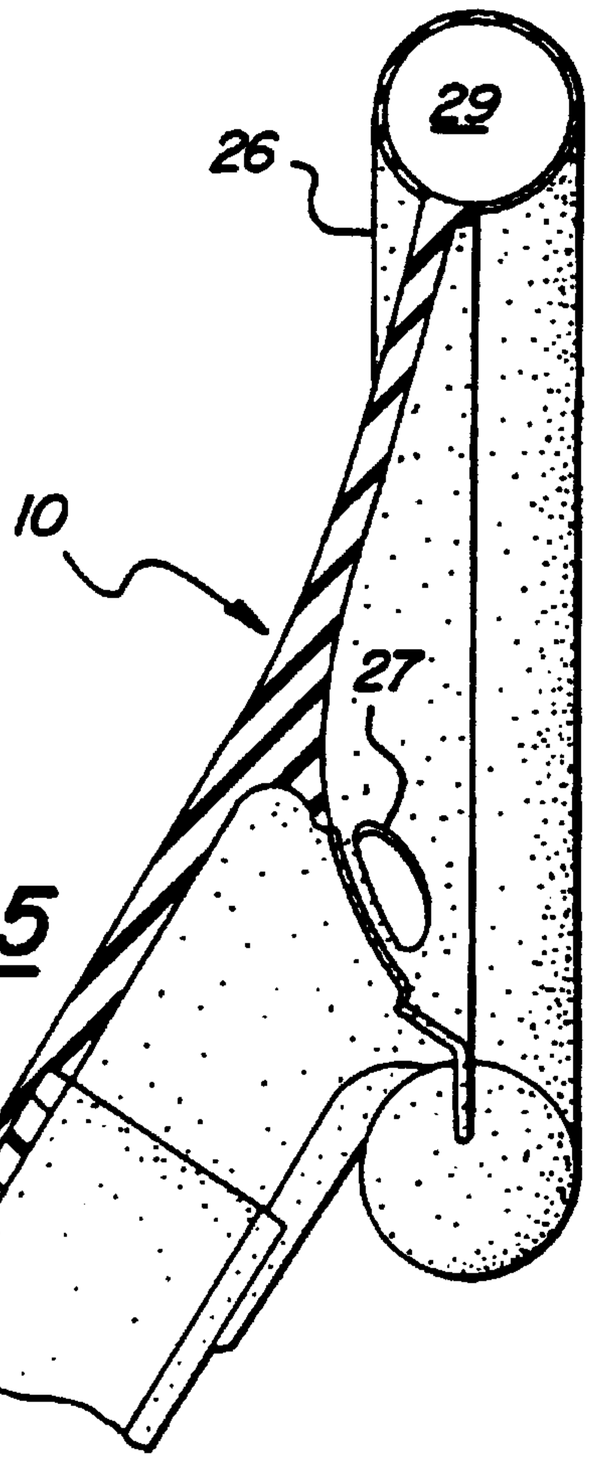
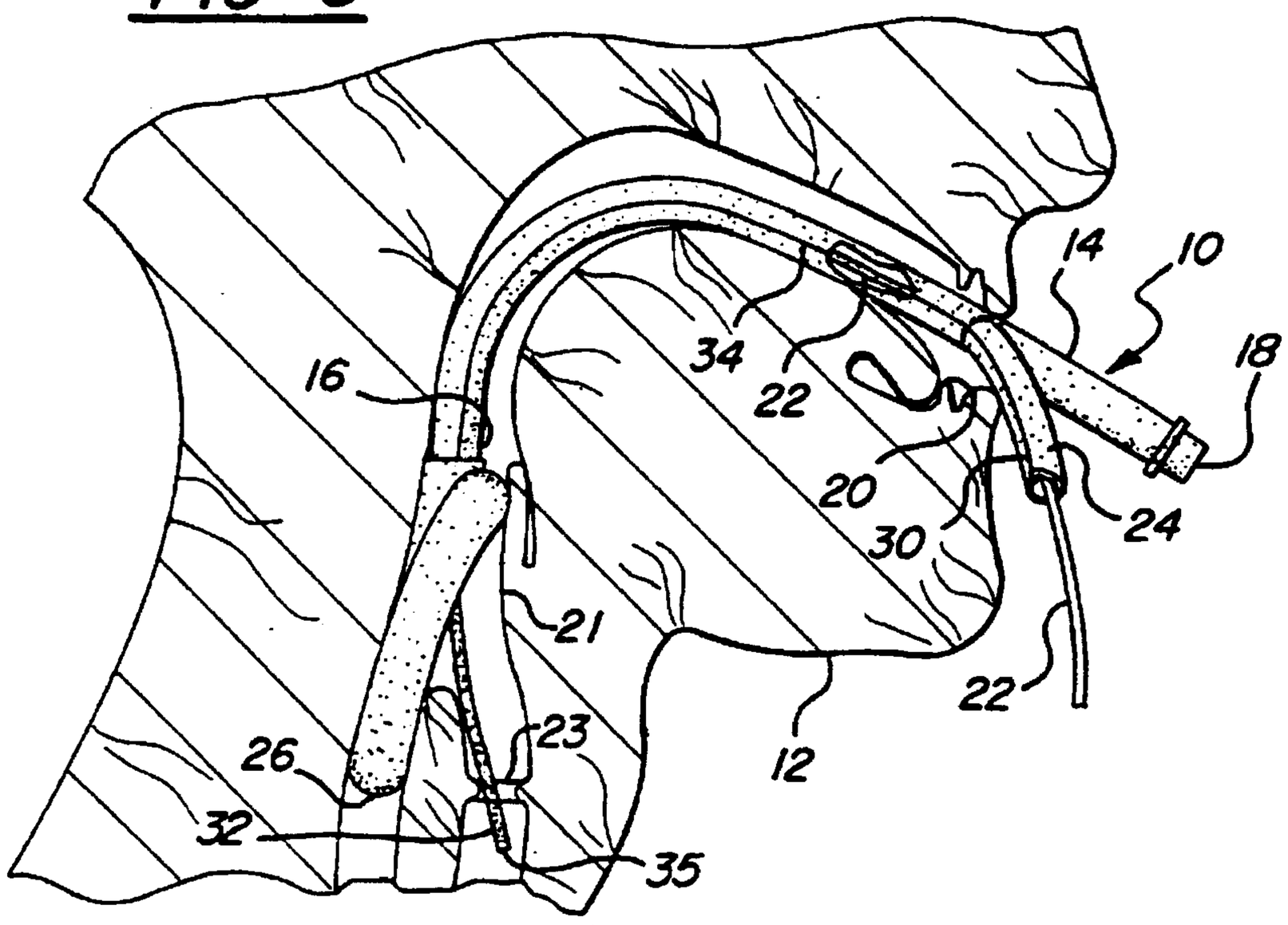


FIG-5

FIG-6



LARYNGEAL MASK ASSEMBLY AND METHOD FOR REMOVING SAME

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

TECHNICAL FIELD

The invention related to artificial airway assemblies. More particularly, the invention relates to artificial airway assemblies which are easily removable after locating the vocal cord of a patient.

DESCRIPTION OF RELATED ART

In recent years, several improvements have been made in the artificial airway technology. U.S. Pat. No. 4,509,514, issued to Brain on Apr. 9, 1985, discloses an artificial airway assembly used to facilitate lung ventilation in an unconscious patient. The laryngeal mask provides a seal around the larynx. A tube connected to the laryngeal mask allows air to pass therethrough and through the mask to facilitate breathing. A pump is used to inflate and deflate the laryngeal mask to facilitate the inserting and removing of the laryngeal airway in the **[**patients**]** *patient's* mouth, as well as to improve the seal around the larynx. Although this artificial airway assembly provides an unblocked airway for an unconscious patient to facilitate the breathing of the patient, the system does not secure the airway in such a manner as an endotracheal tube which resides in the trachea and prevents aspiration of gastric contents in a more definitive manner.

SUMMARY OF THE INVENTION AND ADVANTAGES

The assembly is an artificial airway assembly for ventilating a patient as well aiding in the tracheal intubation of patients in which traditional procedures would be difficult. The artificial airway assembly comprises a flexible airway tube having a patient insertion end and a breathing tube receiving end. The flexible airway tube allows a scoping instrument to pass therethrough to an operating position to view the vocal cords and trachea of the patient. A mask is fixedly secured to the patient insertion end of the flexible airway tube wherein the mask is capable of conforming to the space immediately adjacent the larynx of the patient to properly position the scope instrument. The artificial airway assembly is characterized by removing means for removing the flexible airway tube from the scope instrument while maintaining the scoping instrument in the operating position.

The advantages associated with the subject invention **[**includes**]** *include* the ability to remove the laryngeal mask from the patient's airway while maintaining the end of the scoping instrument in position in the trachea , allowing an endotracheal tube to be guided over the scoping instrument, thereby securing the airway in a definitive manner and allowing for ventilation through the endotracheal tube and prevention of aspiration of gastric contents.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. **1** is a top view of the preferred embodiment of the subject invention;

FIG. **2** is a top view partially cut away of the mask of the preferred embodiment of the subject invention;

FIG. **3** is a cross-sectional view taken along **[**lines**]** *line* **3—3** of *the artificial airway tube of* FIG. **1**;

FIG. **4** is a cross-sectional view **[**of**]** *similar to FIG. 3, for* an alternative embodiment of the artificial airway tube;

FIG. **5** is a cross-sectional view *in longitudinal section* taken along **[**lines**]** *line* **5—5** of FIG. **2**; and

FIG. **6** is a side view partially cut away of a patient with the preferred embodiment of the subject invention inserted in the operating position.

DETAILED DESCRIPTION OF THE DRAWINGS

[Turning to the enclosed sketches,**]** *Referring to the drawings,* an artificial airway assembly is generally shown at **10**. The artificial airway **10** ventilates a patient while when the patient **12** **[**can not breath**]** *cannot breathe* on *his or* her own or needs some form of respiratory assistance. Typically, this occurs when the patient **12** is unconscious during surgery. The artificial airway assembly **10** comprises a flexible airway tube **14**. The flexible airway tube **14** includes a patient insertion end **16** and a breathing tool receiving end **18**. The patient insertion end **16** is inserted into the patient's mouth **20** and extended into a position adjacent the larynx **21**, *specifically the laryngeal inlet.* The breathing tool receiving end **18** is attached to a breathing tool (not shown) such as a ventilating bag or a ventilating machine.

The flexible airway tube **14** allows a scoping instrument **22** to pass therethrough to an operating position to view the vocal cords **23** and trachea **35** of the patient **12**. In the preferred embodiment, the scoping instrument **22** is **[**fiber**]** *a fiber*-optic scope which extends along the length of the flexible airway to a tube **14** and out the patient insertion end **16** to view the vocal cords **23** and enter the trachea **35**. The flexible airway tube **14** includes a second branch **24** which is in fluid communication with the flexible airway tube **14**. The second branch **24** guides the scoping instrument **22** into the flexible airway tube **14** and allows for uninterrupted ventilation to continue through the breathing tool receiving end **18**. The scoping instrument **22**, i.e., the fiber optic scope, is not part of the subject invention wherein any type of scoping instrument may be used to determine the location of the patient insertion end **16**.

A mask **26** is fixedly secured to the patient insertion end **16** of the flexible airway tube **14**. The mask includes holes **27** allowing air and the scoping instrument **22** to pass therethrough. The mask **26** is capable of conforming to the space immediately adjacent the larynx **21** of the patient **12** to properly position the scoping instrument **22**. More specifically the mask **26** is made of a resilient rubber-like material **[**having **]** *in the form of a peripheral ring defining* a hollow space **29** capable of being inflated and deflated to accommodate for the space adjacent the larynx **21**. Because the mask **26** is resiliently deformable, the natural configuration of the mask **26** **[**is in the deflated position**]** *when installed, is that of inflated resilient conformance to the profile of the laryngeal inlet, generally as suggested by FIG. 6*. A valve assembly **28** allows air to pass in and out of the mask **26** which allows for easier insertion when the mask **26** is deflated and a better seal around the larynx **21** when the mask **26** is inflated. Typically, air is injected or withdrawn from the mask **26** with a syringe. The inflatable portion of the mask **26** has ends **40,41** which come together and abut upon inflation of the mask **26** to provide a *peripheral* seal.

In the deflated position, the ends **40**, **41** move away from each other to facilitate removal of the device **10** and the scoping instrument **22**.

The subject invention is characterized by removing means **30** for removing the flexible airway tube **14** and the mask **26** from the scoping instrument **22** while maintaining the scoping instrument **22** in the operating position as shown in FIG. **6**. Once the scoping instrument **22** is in place, artificial airway assembly **10** is removed, a smaller flexible airway tube (not shown) can be manipulated to pass over the **[**fiber optic**]** *fiberoptic* scope into the same position as the end **32** of the scoping instrument **22**, *it being understood that the smaller flexible airway tube may be a commercial endotracheal tube having its own inflatable cuff to secure the patient's airway*. Therefore, once the smaller airway tube is inserted into the same position as the scoping instrument end **32**, the scoping instrument is removed and the airway is secure.

The removing means **30** includes a slit **34** extending along the flexible airway tube **14** **[**and**]**, *through* a position **31** of the mask **26**, *and extending to the central hole 27*. The slit **34** allows the artificial airway assembly **10** to be removed from the scoping instrument **22** while the scoping instrument **22** remains operational in the operating position. The slit **34** creates two opposing side edges **36**, **38**. The opposing side edges **36**, **38** **[**over lap**]** *overlap* each other such that the artificial airway assembly **10** is substantially sealed between the patient insertion end **16** and the breathing tool receiving end **18**.

As may be seen in *the alternative embodiment of* FIG. **4**, the removing means **30** may comprise a scored portion **40** which is weakened at that point allowing the assembly **10** to be torn **[**away**]** *along the weakened alignment 40* when **[**pressure**]** *an extracting force* is applied to the assembly **10** to pull the assembly **10** away from the scope instrument **22**.

In operation, the method for intubating a patient **12** using an artificial airway assembly **10** which includes a mask **26** and a flexible airway tube **14** and a scoping device **22** comprises the steps of: inserting the artificial airway assembly **10** into the mouth **20** of the patient while positioning the mask **26** adjacent the larynx **21**, *thus sealing the airway tube for exclusive communication via the laryngeal inlet*; moving the scoping device **22** through the artificial airway assembly **10** *via branch 24* and the mask **26** into the trachea **35**; removing the artificial airway assembly **10** from the mouth **20** of the patient **12**; and peeling the artificial airway assembly **10** off the scoping device **22**. The peeling of the artificial airway assembly **10** off the scoping deice **22** occurs **[**when**]** *outside the patient and while* the scoping device is maintained in the operating position and while the scoping device **22** is operating.

The invention has been described in an illustrative manner, and it is to be understood that the terminology which has been used is intended to be in the nature of words of description rather than of limitation.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims wherein reference numerals are merely for convenience and are not to be in any way limiting, the invention may be practiced otherwise than as specifically described.

We claim:

1. An artificial airway assembly (**10**) for ventilating a patient (**12**) and utilizing a scoping device in the airway of a patient, said artificial airway assembly (**10**) comprising:

a flexible airway tube (**14**) having a patient insertion end (**16**) and a breathing tool receiving end (**18**), said flexible airway tube having **[**pass through**]** *a branching pass-through* means (*24*) for allowing a scoping instrument (**22**) to pass therethrough *and for guiding the scoping instrument* to an operating position to view vocal cords and trachea of the patient (**12**);

a mask (**26**) fixedly secured to said patient insertion end (**16**) of said flexible airway tube (**14**), said mask (**26**) having conforming means for conforming to a space immediately adjacent the larynx of the patient (**12**) to properly position the scoping instrument (**22**), said artificial airway assembly (**10**) characterized by removing means (**[3]***30*) for removing said flexible airway tube (**14**) and mask (**26**) from the scoping instrument (**22**) while maintaining the scoping instrument (**22**) in the operating position.

2. An assembly (**10**) as set forth in claim **1** further characterized by said removing means (**30**) including a slit (**34**) extending *distally along said pass-through means* (*24*) *and distally continuously from said pass-through means* along said flexible airway tube (**14**).

3. An assembly (**10**) as set forth in claim **2** further characterized by said slit (**34**) extending through a portion of said mask (**26**).

4. An assembly (**10**) as set forth in claim **3** further characterized by said slit (**34**) creating two opposing side edges (**36**, **38**).

5. An assembly (**10**) as set forth in claim **4** further characterized by said two opposing side edges (**36**, **38**) overlapping each other such that said artificial airway assembly (**10**) is substantially sealed between said patient insertion end (**16**) and said breathing tool receiving end (**18**).

[6. An assembly (**10**) as set forth in claim **5** further characterized by said flexible airway tube (**14**) including a second branch (**24**) in fluid communication with said flexible airway tube (**14**) for guiding the scoping instrument (**22**) into flexible airway tube (**14**).**]**

7. A method for intubating a patient (**12**) using an artificial airway assembly (**10**) including a mask (**26**) and flexible airway tube (**14**) *having a branching pass-through guide passage which communicates with the flexible airway assembly between a breathing-tool receiving end and a patient-insertion end of the artificial airway assembly* (*10*), and a scoping device (**22**), the method comprising the steps of:

(*a*) inserting the artificial airway assembly (**10**) into the mouth (**20**) of a patient (**12**);

(*b*) positioning the mask (**26**) adjacent the larynx;

(*c*) *initiating ventilation of the patient via the breathing-tool receiving end;*

(*d*) moving the scoping device (**22**) through the *branching pass-through guide passage* (*24*) *at least to the patient-insertion end of the* artificial airway assembly (**10**) and the mask (**26**);

(*e*) removing the artificial airway assembly (**10**) from the mouth (**20**) of the patient (**12**); and

(*f*) peeling the artificial airway assembly (**10**) off the scoping device (**22**).

8. The method of claim 7, in which step (*d*) *includes moving the scoping device beyond the mask* (*26*) *and into the trachea of the patient.*

9. An assembly (*10*) *as set forth in claim 1, further characterized by said removing means* (*30*) *including a continuously elongate locally weakened and tearable course extending the length of said pass-through means* (*24*) *from*

the receiving end thereof to the patient-insertion end (16) of the flexible airway tube (14).

10. An assembly (10) as set forth in claim 3, in which said mask (26) has a hole (27) for establishing a ventilating passage between the flexible airway tube (14) and the larynx, and the conforming means of said mask (26) comprises an inflatable ring for establishing an initial peripherally sealing engagement of the mask at the laryngeal inlet, said slit (34) extending to at least one of said holes and said inflatable ring being characterized by a local split between peripherally confronting ends of the slit portion of said mask (26).

11. An artificial airway assembly (10) for ventilating a patient (12) and utilizing a scoping device in the patient's airway, said artificial airway assembly (10) comprising:

a flexible airway tube (14) having a patient-insertion end (16) and a breathing-tool receiving end (18) and a pass-through receiving end (24), said pass-through receiving end (24) being adapted to allow a scoping instrument (22) to pass therethrough to an operating position at the patient-insertion end (16) of said tube to view vocal cords and trachea of the patient (12), said breathing-tool receiving end (18) and said pass-through receiving end (24) having separate merging communication with said airway tube at a location intermediate said patient-insertion end (16) and said receiving ends (18, 24);

a mask (26) fixedly secured to said patient-insertion end (16) of said flexible airway tube (14), said mask (26) having conforming means for conforming to a space immediately adjacent the larynx of the patient (12) to properly position the scoping instrument (22), said artificial airway assembly (10) being characterized by

removing means (30) for removing said flexible airway tube (14) and mask (26) from the scoping instrument (22) while maintaining the scoping instrument (22) in the operating position.

12. An artificial airway assembly (10) for ventilating a patient (12) and utilizing a scoping device in the airway of a patient, said artificial airway assembly (10) comprising:

a flexible airway tube (14) having a patient-insertion end (16) and a breathing-tool receiving end (18) and a pass-through receiving end (24), said pass-through receiving end (24) being adapted to allow a scoping instrument (22) to pass therethrough to an operating position at the patient-insertion end (16) of said tube to view vocal cords and trachea of the patient (12), said breathing-tool receiving end (18) and said pass-through receiving end (24) having separate merging communication with said airway tube at a location intermediate said patient-insertion end (16) and said receiving ends (18, 24);

a mask secured to the patient-insertion end of the flexible airway tube, said mask having an opening (27) for patient ventilating passage therethrough,

removing means (30) for removing said flexible airway tube and mask from the scoping instrument while maintaining the scoping instrument in the operating position, said removing means being characterized by an elongate continuous slit from said pass-through receiving end (24) to said mask opening (27) and via an intervening length of said flexible airway tube,

said mask (26) including an inflatable ring for peripheral sealing of said mask at the laryngeal inlet, said inflatable ring being characterized by a split at the location of slit passage in said mask to the mask opening, the split of said ring defining confronting peripheral ends which inflate in patient-installed position into sealed relation to each other and thus into peripherally continuous sealed relation to the laryngeal inlet.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : Re. 35,531
DATED : June 17, 1997
INVENTOR(S) : Eric B. CALLAGHAN and Mark L. CALLAGHAN

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, item [56] **References Cited**

FOREIGN PATENT DOCUMENTS

Line 3, after "685295 11/1991"
delete "United Kingdom"
and insert therefor --U.S.S.R.--

OTHER PUBLICATIONS

Line 12, delete "Fibrooeptic"
and insert therefor --Fibreoptic--

Column 3, line 11; before "scope" delete "fiberoptic"
and insert therefor --fiber-optic--

Column 3, line 48; delete "deice 22"
and insert therefor --device 22--

Signed and Sealed this

Fourteenth Day of October, 1997

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks