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**A5R RGEX**

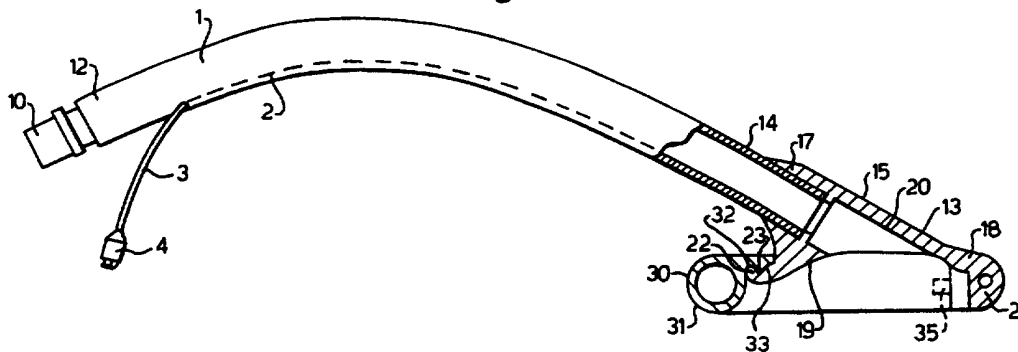
(56) Documents Cited  
**None**

(58) Field of Search  
UK CL (Edition P ) **A5R RGAA RGEX**  
INT CL<sup>6</sup> **A61M 16/00 16/04**

(54) Abstract Title  
**Laryngeal mask**

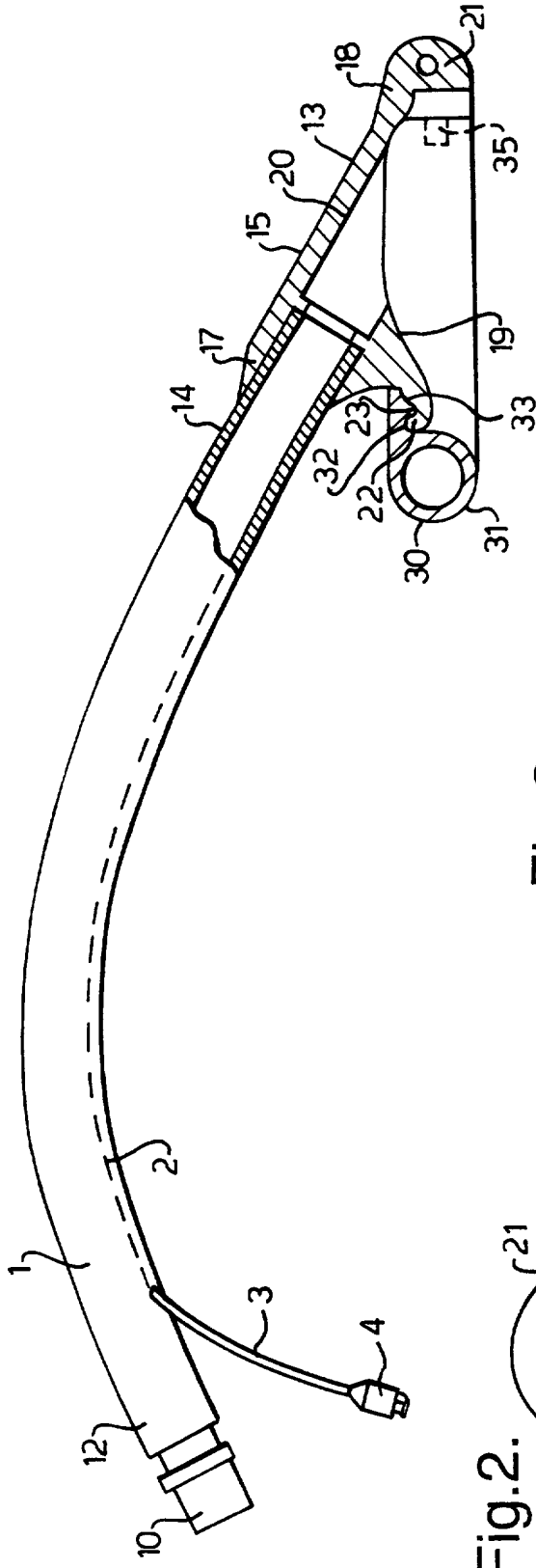
(57) A laryngeal mask has a mount 15 at its patient end of elliptical shape supporting an inflatable cuff 30. The cuff 30 is a hollow extruded tube with an integral attachment flange 32 and has opposite ends receiving two spigots 35 on the mount 15. The attachment flange 32 is attached to the mount 15 by means of a projecting tooth 33, which locates in a channel 23 around the mount.

**Fig.1.**



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Fig.1.



Σ

Fig.2.

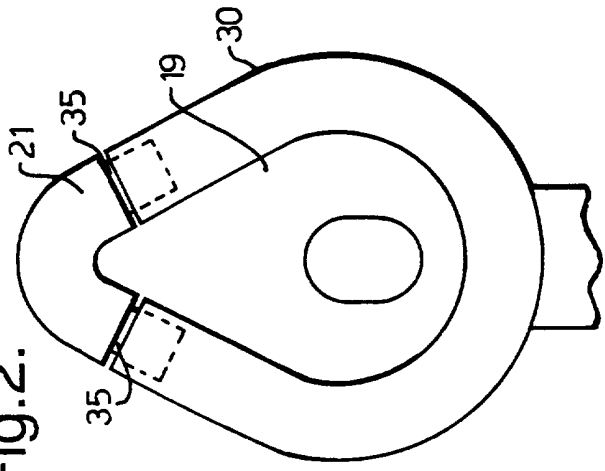


Fig.3.

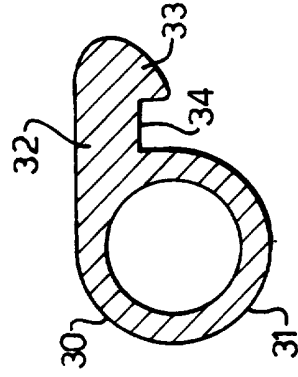
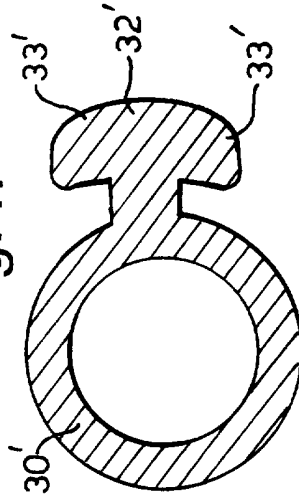


Fig.4.



**LARYNGEAL MASK AIRWAYS AND THEIR MANUFACTURE**

This invention relates to laryngeal mask airways and their manufacture

It is common practice to use an airway known as a laryngeal mask for the administration of anaesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are described in, for example, US 5355879, US 5305743, US 5297547, US 5282464, GB 2267034, US 5249571, US 5241956, US 5303697, GB 2249959, GB 2111394, EP 448878, US 4995388, GB 2205499, GB 2128561 and GB 2298797.

Laryngeal masks have several advantages over endotracheal tubes, which are longer and seal with the trachea below the vocal folds. It can be difficult, however, to manufacture the patient end of the mask at low cost.

It is an object of the present invention to provide an improved laryngeal mask assembly and method of manufacture.

According to one aspect of the present invention there is provided a laryngeal mask assembly comprising an elongate tube and a mask portion at the patient end of the tube, the mask portion including a mount member of generally elliptical shape having an opening therethrough communicating with the patient end of the tube and a hollow cylindrical cuff member extending around the mount member and attached with the mount member by an attachment flange projecting laterally of the cuff member along its length.

The mount member preferably has two spigots, opposite ends of the cuff member being open and mounted on respective ones of the spigots. At least one of the spigots preferably communicates with an inflation lumen extending along the tube so that the cuff member can be inflated via the lumen and the or each spigot. The attachment flange of the cuff member may have a projecting member extending along its length defining a channel between the projecting member and a tubular portion of the cuff member. The mount member may have a channel extending around its outer edge, the projecting member on the attachment flange being located in the channel on the mount member. Alternatively, the attachment flange may be of arrow shape in section.

According to another aspect of the present invention there is provided a method of manufacture of a laryngeal mask assembly including the steps of providing an elongate tube having a mount member at its patient end, the mount member being of generally elliptical shape and having an opening therethrough communicating with the patient end of the tube, providing a hollow cylindrical cuff member having an attachment flange projecting laterally of the cuff member along its length, folding the cuff member about an outer edge of the mount member, and attaching the attachment flange to the mount member.

The cuff member is preferably extruded.

According to a further aspect of the present invention there is provided a laryngeal mask assembly made by a method according to the other aspect of the present invention.

A laryngeal mask airway assembly and its method of manufacture, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figure 1 is a partly-sectional side elevation view of the assembly;
- Figure 2 is an underside view of the patient end of the assembly;
- Figure 3 is a transverse cross-side view, to an enlarged scale, of the cuff;  
and
- Figure 4 is a transverse cross-side view, to an enlarged scale, of an alternative cuff.

With reference to Figures 1 to 3, the assembly comprises a bendable tube 1 of a plastics material, such as PVC, with a coupling 10 at its machine end 12. The tube 1 is curved along its length and has a mask portion 13 at its patient end 14.

The tube 1 is extruded with an inflation lumen 2 within its wall. The lumen 2 is connected towards the machine end of the assembly to an inflation line 3 with an inflation indicator and connector 4. The opposite, patient end of the inflation lumen 2 communicates with the mask portion 13.

The mask portion 13 includes a mount member 15 moulded from a relatively stiff plastics material, such as PVC. The mount member 15 has a hollow cylindrical sleeve 17 at its rear end, in which the forward, patient end 14 of the tube 1 is inserted and joined. The forward, patient end 18 of the mount member 15 is of an inverted dish shape with a generally

elliptical or egg-shape outline and with a concave recess 19. A bore 20 extends forwardly through the mount member 15, as a continuation of the bore through the sleeve 17, and opens into the rear part of the recess 19. The forward surface of the mount member 15 has a projection 21 of inverted V-shape at its forward tip, the purpose of which will become apparent later. The rear surface of the mount member 15 has an upwardly-projecting lip 22 extending around the major part of its periphery and, within the lip, a recessed channel 23.

The mask portion 13 also includes an inflatable cuff 30 attached around the edge of the mount member 15. The cuff 30 is extruded from a flexible, resilient plastics material, such as PVC, polyurethane, silicone, EVA, TPE, polyether block amide or the like. The main part of the cuff 30 is provided by a tubular portion 31 of circular section. The cuff 30 also has an integral flange or attachment member 32 projecting laterally outwardly from the tubular portion 31 along its length. The outer end of the flange 32 has a downwardly-projecting tooth 33, which defines a channel 34 along the underside of the flange, between the tubular portion 31 and an inner edge of the tooth. The cuff 30 could be made by other techniques such as pulsed (bubble) extrusion or blow moulding, or by a combination of extrusion and subsequent blow moulding to produce regions of reduced wall thickness and different diameters. The cuff 30 is folded around the outer edge of the mount member 15, with its flange 32 projecting inwardly and overlapping the outer edge of the mount member. In particular, the tooth 33 on the flange 32 locates in the channel 23 in the mount member 15, and the lip 22 on the mount member locates in the channel 34 on the flange. Opposite ends of the cuff 30 are fitted over two spigots 35 protruding from opposite arms the projection 21 on the mount member 15. A solvent, adhesive or heat bond is used to join the contacting surfaces of the cuff 30 and mount member 15 to one another.

The cuff 30 can be inflated and deflated in various different ways. For example, the projection 21 and spigots 35 could be hollow and communicate with the inflation lumen 2 via

a gas passage formed in the mount member 15, so that gas can be supplied to or from opposite ends of the cuff 30. Alternatively, a separate small-bore tube could be connected between the inflation lumen and the interior of the cuff.

The cuff could have various different sections, thus controlling the shape of the cuff when deflated by the application of a vacuum, for insertion into the patient. For example, as shown in Figure 4, the cuff 30' has a flange 32' of arrow-head shape with two oppositely-projecting teeth 33'. This flange 32' can be a snap fit into a recess (not shown) in the mount member of a corresponding shape. The ends of the cuff need not be joined at the tip of the mount member but could instead be joined at the opposite end or heel.

The cuff could be filled with a foam to make it self-inflating and negative pressure applied via the lumen 2 to suck down the cuff for insertion and removal.

CLAIMS

1. A laryngeal mask assembly comprising an elongate tube and a mask portion at the patient end of the tube, wherein the mask portion includes a mount member of generally elliptical shape having an opening therethrough communicating with the patient end of the tube and a hollow cylindrical cuff member extending around the mount member and attached with the mount member by an attachment flange projecting laterally of the cuff member along its length.
2. A laryngeal mask assembly according to Claim 1, wherein the mount member has two spigots, wherein opposite ends of said cuff member are open, and wherein the open ends of said cuff member are mounted on respective ones of said spigots.
3. A laryngeal mask assembly according to Claim 2, wherein at least one of said spigots communicates with an inflation lumen extending along said tube so that the cuff member can be inflated via the lumen and the or each spigot.
4. A laryngeal mask assembly according to any one of the preceding claims, wherein said attachment flange of said cuff member has a projecting member extending along its length defining a channel between said projecting member and a tubular portion of said cuff member.



5. A laryngeal mask assembly according to Claim 4, wherein said mount member has a channel extending around its outer edge, and wherein the projecting member on said attachment flange is located in the channel on said mount member.
6. A laryngeal mask assembly according to any one of Claims 1 to 3, wherein the said attachment flange is of arrow shape in section.
7. A laryngeal mask assembly substantially as hereinbefore described with reference to Figures 1 to 3 of the accompanying drawings.
8. A laryngeal mask assembly substantially as hereinbefore described with reference to Figures 1 to 3 as modified by Figure 4 of the accompanying drawings.
9. A method of manufacture of a laryngeal mask assembly including the steps of providing an elongate tube having a mount member at its patient end, the mount member being of generally elliptical shape and having an opening therethrough communicating with the patient end of the tube, providing a hollow cylindrical cuff member having an attachment flange projecting laterally of the cuff member along its length, folding the cuff member about an outer edge of the mount member, and attaching the attachment flange to the mount member.

10. A method according to Claim 9, wherein said cuff member is extruded.
11. A method of making a laryngeal mask assembly substantially as hereinbefore described with reference to Figures 1 to 3 of the accompanying drawings.
12. A method of making a laryngeal mask assembly substantially as hereinbefore described with reference to Figures 1 to 3 as modified by Figure 4 of the accompanying drawings.
13. A laryngeal mask assembly made by a method according to any one of Claims 9 to 12.
14. Any novel and inventive feature as hereinbefore described.



Application No: GB 9800271.0  
Claims searched: 1-13

Examiner: Anwar Gilani  
Date of search: 8 April 1998

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.P): A5R (RGEX, RGAA)

Int CI (Ed.6): A61M 16/00, 16/04

Other: Online: WPI

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
	NONE	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.