

**ENDOTRACHEAL-TUBE GUIDANCE
SYSTEM WITH EPIGLOTTIS-ELEVATING
FEATURE**

RELATED CASE

This application is a continuation of copending original application, Ser. No. 08/641,957, filed May 2, 1996 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to an endotracheal-guidance system, such as an artificial airway device, or laryngeal-mask airway (LMA) device, of the type that finds use in anaesthetic procedures.

Patent No. GB 2,205,499 describes a miniature mask attached to a tube designed to fit into the lower throat as a means of securing the airway of an unconscious patient during anaesthesia. Such devices have met with quite remarkable success and are currently used in some 50 percent of general anaesthetic procedures in the United Kingdom. The use of such masks continues to spread throughout the world. The principal advantages associated with the use of such a mask are the simplicity of its installation and uses, the freeing of the anaesthetist's hands, and the lack of trauma to airway structures, as compared with the conventional and more traditional endotracheal tube (ET).

An important limiting factor in the use of the LMA device is its failure to adequately protect the lungs of an unconscious patient when regurgitation of stomach contents unexpectedly occurs. An endotracheal tube (ET), once placed in the windpipe, is still considered to be the definitive solution to this problem in patients at risk. However, it is sometimes difficult or even impossible to correctly position an ET owing to anatomical factors which may be unpredictable, and there is therefore always a risk that intubation of the windpipe will fail. This has resulted in death or brain damage of previously completely healthy people. While the LMA device can prevent this disaster, if there is also a risk of stomach contents entering and damaging the lungs (for example, in the case of anaesthesia for Caesarian Section), then most practitioners will want to subsequently achieve insertion of an ET even if disaster has been averted by supplying oxygen to the lungs via an LMA device.

This requirement has led to the design of a special LMA device (see, for example, U.S. Pat. No. 5,303,697) adapted to serve as guidance means to allow insertion of the appropriate size of ET. Indeed, the standard LMA device will permit insertion of a rather small-size ET, although the technique is not always successful, and it may subsequently be necessary to exchange the small ET for a larger one; such an exchange is a somewhat complicated and often difficult procedure, which is not without risk to the patient. The reason why it is not always possible to pass an ET through an LMA device into the windpipe (trachea) can only be understood by reference to an anatomical structure known as the epiglottis, which is in effect a cartilaginous shield attached to the upper border of the opening into the larynx (the glottis).

The epiglottis has an important function in directing the flow of food or drink when swallowed so that the flow does not accidentally spill into the windpipe or trachea via the glottic opening. The epiglottis is a hinged structure which swings down somewhat like a visor over the glottis during the action of swallowing. When the LMA device is placed in the lower throat (hypopharynx), the epiglottis is pushed

forward, and its rim is held away from the LMA mask aperture by two bars, the mask-aperture bars (MABs). The MABs prevent the flap-like epiglottis from folding down to obstruct the passage of gas through the mask aperture, and in practice they fulfil this function reliably without traumatizing the epiglottis. However, in order to pass an ET through the mask aperture of the LMA and into the glottis and trachea, it is sometimes necessary for the epiglottis to be lifted further upwards (swung further out of the way of the aperture) than can be achieved with the current design of MABs. Indeed, the MABs are not designed to force the epiglottis away from its normal anatomical neutral position in the airstream, and it is therefore not surprising that it may be difficult to pass a tube under the epiglottis to get it into the glottic opening even though gas may be passing freely through the LMA into the patient's lungs.

Normally, this problem can be solved by use of a fibroscope, which is a bendable light source and telescope which permits the anaesthetist to directly view the structures described and then thread an ET over the fibroscope and into the trachea. However, such direct-viewing equipment is expensive, and the procedure may be time-consuming. In matters pertaining to management of the airway of unconscious patients, time is of the essence, in that four minutes without oxygen is enough to cause brain damage.

MABs of current design consist of twin parallel bars of soft silicone material which (1) are sufficiently pliable to readily deflect and thus to allow passage of an object up to the diameter of the mask aperture itself, but which (2) are firm enough to resist penetration of the aperture by the epiglottis, which is caught up against them, rather like a fish caught in a net. Two bars have been used rather than some other number such as three or one, so that any tube passing through will not encounter a central bar and will thus not be deviated to one side (of a central bar), while a greater number than three bars would unnecessarily increase resistance to gas flow.

BRIEF STATEMENT OF THE INVENTION

It is a first principal object of the invention to provide an improved LMA construction which will materially reduce the chance of epiglottis interference with the path of LMA-guided insertion of an endotracheal tube (ET) or other LMA-guided instrumentation. It is a second principal object of the invention to provide an improved guidance system for guided insertion of an endotracheal tube (ET) or other guided instrumentation, wherein a structural feature at the distal end of the guidance system will materially reduce the chance of epiglottis interference with the path of guided insertion of the system-guided instrumentation.

A specific object is to meet the first above-stated object with an LMA construction, wherein a displaceable part of the LMA can be automatically so actuated by the insertional approach of an ET or other LMA-guided instrument, that the epiglottis is caused to be displaced out of the insertional path of the ET or other LMA-guided instrument.

Another specific object is to provide improved LMA structure of the character indicated with means for more correctly directing the advancing distal end of ET or other airway-guided instrumentation after it has emerged from the airway tube of the LMA.

A further specific object is to provide improved LMA structure which can better assure that an ET or other LMA-guided instrumentation intended for passage to or through the glottic opening cannot be inadvertently inserted into the oesophagus or the hypopharynx.