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A61M 16/04

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(56) Documents Cited

GB 1017515 A	**JP 010024043 A**	**US 5862801 A**
US 5699787 A	**US 5590643 A**	**US 5009227 A**
US 4640273 A	**US 4344428 A**	**US 4166467 A**

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INT CL[7] **A61M 16/04**
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(54) Abstract Title
Safety device for laryngeal mask airway or endotracheal tube

(57) A hollow tubular ring (1) is slotted over the laryngeal mask airway (3) or endotracheal tube to prevent the biting down action of the awakening patient from occluding the lumen of the laryngeal mask airway or endotracheal tube and thus preventing the flow of oxygen to the patient. The tubular ring preferably has an internal diameter slightly greater than the external diameter of the appropriate sized laryngeal mask airway or endotracheal tube, and an external diameter between one and a half and three times greater than its internal diameter. The wall (2) of the ring may be filled with a firm substance, which is also soft enough to prevent damage to dental work, for instance, the gel used in head rings in theatre for anaesthetised patients, encased in rubber. The ring can either be autoclaved after use, or disposed of, depending on the materials used.

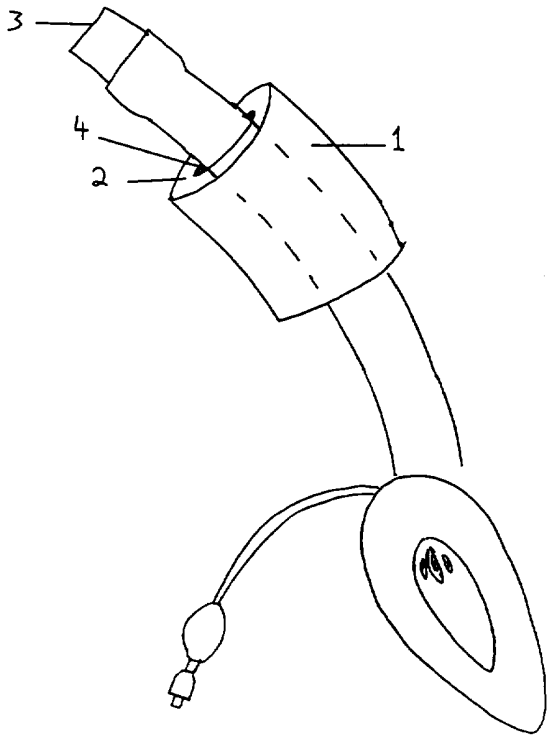

Figure 5

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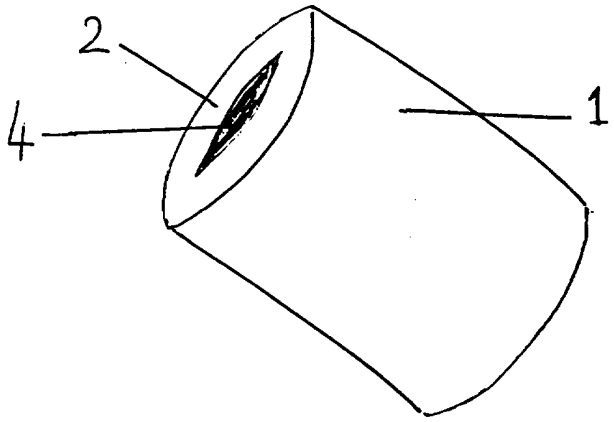

Figure 1

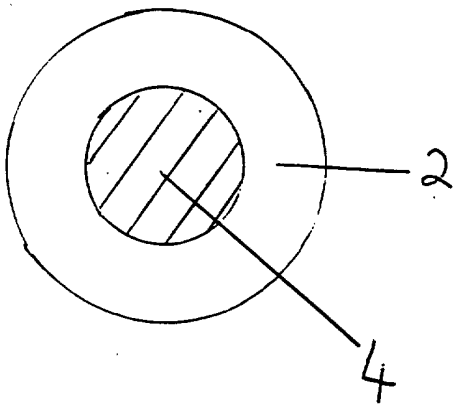

Figure 2

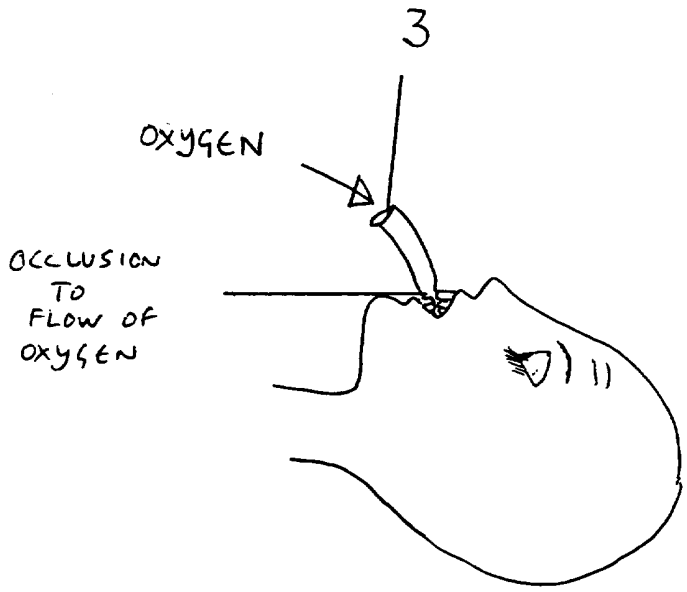

Figure 3

3

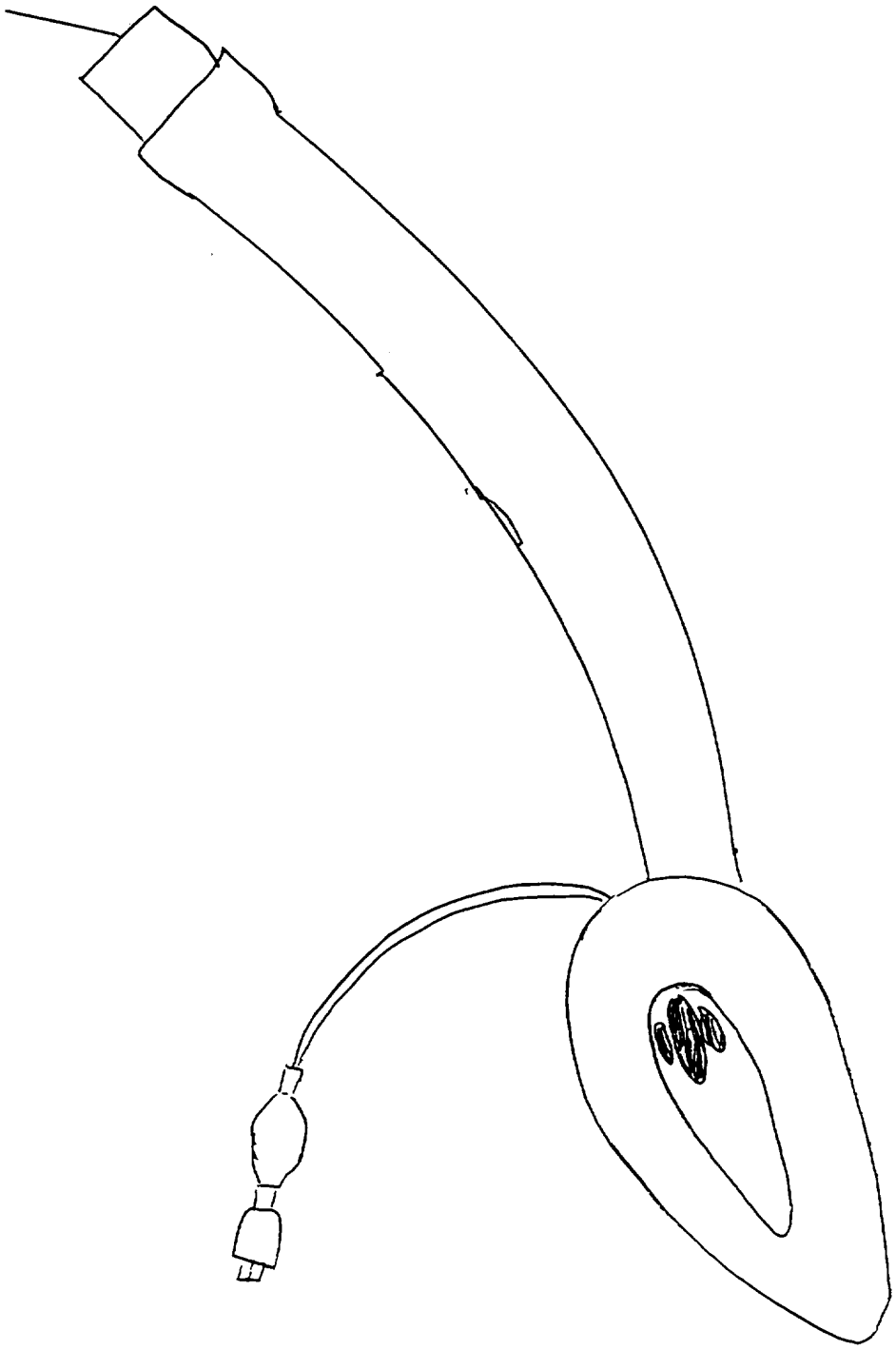

Figure 4

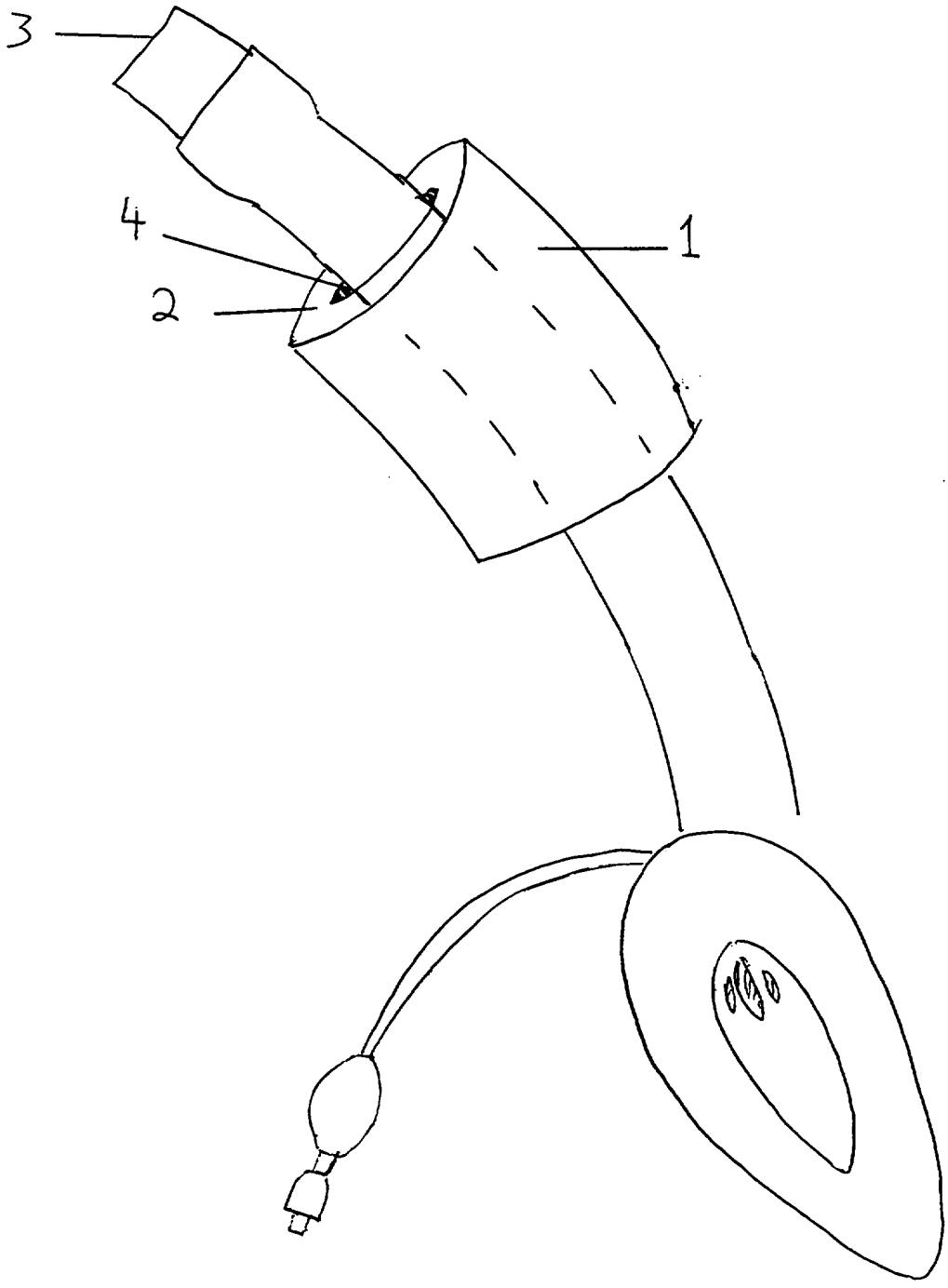

Figure 5

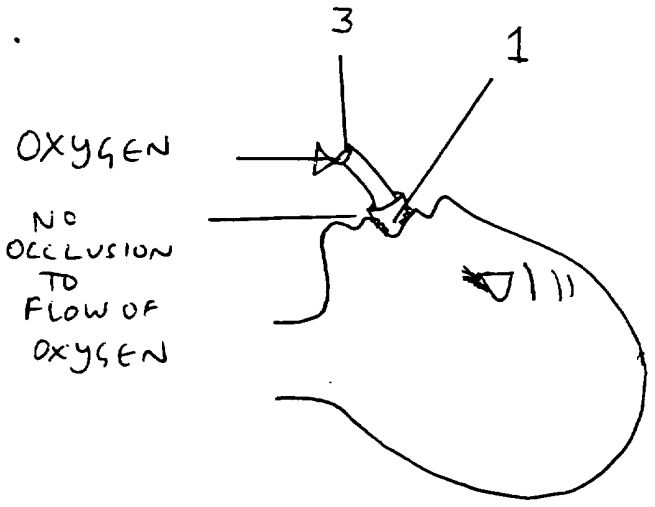

Figure 6

Patent Specification for Safety Device for Laryngeal Mask Airway or Endotracheal Tube

This invention relates to a protective hollow tubular ring made of rubber or a similar sbstance and with a wall filled with soft gel-like material, which slots over the laryngeal mask airway (LMA) or the endotracheal tube (ETT) once the LMA or ETT is in position in the anaesthetised patient. The device is designed to prevent the semi-conscious, anaesthetised patient from biting through the laryngeal mask airway (LMA) or endotracheal tube (ETT). Biting through the LMA or ETT causes obstruction to gas flow through said LMA or ETT, and therefore stops oxygen from reaching the patient. It is a frequent cause of hypoxia (ie oxygen starvation) in the patient who is awakening after an anaesthetic.These episodes are usually transient, but occasionally more prolonged. As well as preventing the potentially deleterious hypoxic episodes that occur when the patient involuntarily bites down on the LMA or ETT, the current invention is soft and malleable so that it prevents damage to the teeth or to dental work such as crowns or caps during these biting down episodes. The most appropriate material for this hollow tubular ring is a gel-filled rubber , ie a short, hollow rubber tube the wall of which is filled with the soft, malleable, yet firm, gel-like material that is used to manufacture operating theatre head-rings for anaesthetised patients.

The laryngeal mask airway (LMA), invented by Brain, has revolutionalised anaesthesia by allowing maintenance of an airway in an anesthetised patient without recourse to either endotracheal intubation, with its attendant risks of failed intubation, adverse reactions to paralysing agents given to allow intubation, etc, or to holding on a face mask for the duration of the procedure, which prevents the anaesthetist from carrying out other tasks during the procedure since it means the anaesthetist must always be physically supporting the face mask and the patient's chin. The LMA has therefore been a huge leap forward in the world of anaesthesia.

However, a major problem with the LMA is that when the procedure is over and the anaesthetised patient is being woken up, the patient goes through a plane of semi consciousness when he/she often bites down on the LMA. This can occur because of pain related to the operation, disorientation, confusion, agitation, or just as a reflex. The clamping down effect of their teeth on the LMA completely obstructs the route by which oxygen reaches the patient, so that neither spontaneous respiration nor assisted ventilation are possible. All methods of getting oxygen to the patient are therefore impossible. The patient becomes blue and hypoxic (oxygen starved). Removing the LMA and restoring the airway is the only means by which this hypoxia can be curtailed. However, removing the LMA is fequently very difficult as it is clenched between the front teeth in a vice-like grip. Pulling the LMA in order to release it also risks damage to the patient's

teeth/ dental work. Telling the patient to stop biting is not any use as they are still half asleep and do not obey commands.

Although these hypoxic episodes are usually only transient, occasionally it proves difficult to prise the LMA out from between the clenched teeth and so the episode of hypoxia is more prolonged and occasionally is only curtailed by resedating the patient with enough intravenous anaesthetic agent to cause relaxation of the jaws, allowing the LMA to be removed. Since the recovery room, where patients recover from anaesthesia, is usually staffed by nurses but not anaesthetists, the potential danger of these biting down episodes is magnified in that there is not always an anaesthetist available immediately to take over the patient's airway or to resedate the patient if this is required.

Placing an oropharyngeal airway such as a Guedel airway next to the LMA is not easy as the LMA has a wide diameter, and placing the oropharyngeal airway adjacent to it but still between the teeth is often not possible because of lack of space. If the oropharyngeal airway is forced in next to the LMA, there is the risk that the LMA may be moved, disturbing the positioning, with the attendant risk of losing the airway, since a clear airway is dependent on precise positioning of the LMA.

This problem is more marked with LMAs than with ETTs, as when endotracheal tubes are used,the narrower diameter and lesser bulk of the endotracheal tube means that there is enough room in the patient's mouth for an oropharyngeal airway to be placed adjacent to the endotracheal tube and between the front teeth, preventing biting down from obstructing gas flow through the endotracheal tube. Nevertheless, even with endotracheal tubes, the problem of damage to dental work remains when the patient bites down onto a hard plastic oropharyngeal airway placed adjacent to the endotracheal tube. The softer material of the current invention means that there is less risk of damage to the teeth if this is used instead of the hard, plastic oropharyngeal airway.

An invention was therefore required that would prevent patients from biting through the LMA or ETT on awakening, and would therefore prevent the potential risk of hypoxia that sometimes occurs at this stage. The invention needed to be made of a soft and malleable material so that there would be negligible risk of damage to dental work when the patient bites down on it. It must also be made either of a material that allows it to be rinsed under the tap and autoclaved in the same way as the LMA, so that it can be sterilised between uses, or of a disposable material, which was firm enough to withstand the biting action of the teeth yet softer than the hard plastic used in oropharyngeal airways.

The current invention consists of a hollow tubular ring which slots over the LMA and is positioned at the level of the front teeth just after the LMA is inserted at induction of anaesthesia. The hollow tubular ring has an external diameter which is between one and a half to three times its internal diameter, and this wall of the hollow tube is filled with a soft, gel-like material.this would be firm yet soft and malleable. However, any other soft, malleable, but firm and durable (withstanding biting), non toxic material would be an alternative. A rubber coating would allow softer material to be used inside the wall of the hollow tubular ring. The hollow tubular ring is either made of a substance that can be rinsed and autoclaved, or a material sufficiently non expensive to allow it to be discarded after a single use. The tubular ring has an internal diameter just wider than the external diameter of the hollow tube of the LMA (or ETT), so that it can be slotted easily over the LMA after the LMA has been inserted and before connection to the catheter mount or the rest of the anaesthetic circuit. The external diameter is between one and a half and three times wider than the internal diameter,depending on the size of the laryngeal mask airway/endotracheal tube with which it is designed to be used, so that the wall of the tubular ring can be filled with a firm but soft material, such as the gel-like substance that is used in manufacturing operating theatre head rings for anaesthetised patients, or an alternative soft but firm substance. This tubular ring is firm enough to prevent the biting down action of the teeth from compressing the hollow rubber tube of the LMA/ ETT, and will therefore prevent the obstruction to air flow that occurs when the patient bites down. At the same time, the tubular ring is soft and malleable, so that biting down on it will not damage the patient's teeth. In this respect, it is superior to the oropharyngeal airway.

After the procedure, the tubular ring can be removed from the LMA and either rinsed and autoclaved in the same way as the LMA, or, if a disposable material is used, the tubular ring is simply discarded after use.

There is no danger of the tubular ring becoming misplaced or disappearing down the patient's mouth/pharynx during the anaesthetic, as it is long enough that several centimetres of it protrude from the patient's mouth, so that it is easily within reach of the anaesthetist or anaesthetic nurse. In addition, its internal diameter will be smaller than that of the inflatable part of the LMA or of the cuff of the endotracheal tube, so that it will not physically be able to come off the LMA or cuffed ETT at the patient end. (In children, in whom uncuffed ETTs are used, the main safety feature in this respect will be the fact that several centimetres protrude from the patient's mouth - the device should never be pushed all the way in to the patient's mouth so that it is not visible from the outside. It may therefore be advisable to make the tubular ring comparatively longer when it is to be used with uncuffed endotracheal tubes, so that this safety feature is greater. Note that with LMAs in children, the tubular ring is unable to pass over the inflatable part of the LMA, so that the theoretical but tiny risk of the tubular

ring passing entirely into the mouth and coming off the far end of the ETT, is only a problem for uncuffed ETTs, and not for LMAs in even the tiniest children.)

The tubular ring is designed to be of adequate length that it is long enough to completely insert between the upper and lower front teeth, and long enough that it will not 'disappear' into the mouth since there must be enough protruding from the mouth to prevent it sliding all the way into the mouth and losing its essential position between the front teeth. The internal diameter is such that it slides easily over the hollow tube of the LMA or ETT. An internal diameter of 2 cm would be ideal for a size 4 LMA; correspondingly smaller or larger internal diameters would be appropriate for smaller or larger LMAs since LMAs come in sizes 1, 1.5, 2, 2.5, 3, 4, and 5, for use in patients ranging from babies to large adults. In the given example, an external diameter of approximately 3.5 cm would allow ample room in the wall of the ring for enough gel to prevent the biting action of the teeth from impinging on the lumen of the laryngeal mask airway. A length of 4 - 5cm would be appropriate for a size 4 LMA; correspondingly longer or shorter ones would be appropriate for the different sizes of LMA. Similarly, several different sizes could be designed for use with different sizes of ETT.

A specific description of the invention will now follow, with reference to the accompanying diagrams:

Figure 1 shows the hollow tubular ring from the side.

Figure 2 shows the hollow tubular ring in cross section.

Figure 3 illustrates the detrimental effect of an anaesthetised patient biting down on the LMA without the current hollow tubular ring invention in position. It may be seen that the lumen of the hollow rubber tube of the LMA is completely occluded by the biting down effect, preventing gas (and most relevantly, oxygen) from getting to or from the patient.

Figure 4 shows the LMA from the side without the current hollow tubular ring invention in position. (LMA not in patient)

Figure 5 shows the LMA from the side with the current hollow tubular ring invention in position. (LMA not in patient)

Figure 6 shows the LMA and current hollow tubular ring invention in position in an anaesthetised patient, with the biting down effect of the patient's teeth blocked by the ring.

Referring to the diagrams, the current invention consists of a hollow tubular ring, 1, the wall of which, 2, is filled with a soft but malleable substance such as a gel-like substance encased in rubber which is firm enough to prevent the clamping

down effect of the front teeth of an anaesthetised patient from occluding the hollow lumen of the laryngeal mask airway (or endotracheal tube), 3. It can be seen in diagram 3 that this biting down effect totally occludes the route by which oxygen reaches the patient when the tubular ring is not in position on the LMA. The hollow lumen of the tubular ring, 4, is wide enough to allow the tubular ring to slide over the hollow tube of the LMA or ETT.

One way of ensuring that the tubular ring is firm enough to protect the lumen of the underlying laryngeal mask airway or endotracheal tube from being obstructed by the clenching down of the patient's teeth, yet soft enough to prevent damage to the patient's teeth (including caps/crowns/bridges), is by constructing the hollow tubular ring so that its innermost wall,ie, that of the smaller circumference/diameter, which lies directly adjacent to and in contact with the LMA or ETT, is made of a hard substance such as hard, non crushable plastic (in a disposable model) or thick, non crushable rubber (in an autoclavable model), while the overlying substance of the ring is made of a softer, more malleable substance such as the gel-like material described.

CLAIMS

1: A hollow tubular ring that may be slotted over the laryngeal mask airway or the endotracheal tube in order to prevent the biting action of the semi-anaesthetised patient from occluding the lumen of the laryngeal mask airway or endotracheal tube and thus preventing oxygen or anaesthetic gases from getting to the patient. The tubular ring is long enough to enable it to be positioned so that it lies completely between the upper and lower front teeth with part of its length visible outside the patient's mouth so that it will not inadvertently slide totally into the mouth and be inaccessible to the anaesthetist or anaesthetic nurse.The material that the tubular ring is made of is firm enough to prevent the biting action of the teeth of the patient from occluding the lumen of the laryngeal mask airway or the endotracheal tube, yet soft enough to prevent damage to dental work during this biting down.

2: A hollow tubular ring as described in claim 1, made of an autoclavable material such as rubber, the wall of which contains a gel-like material, such as that used in the manufacture of the head rings used in the operating theatre for anaesthetised patients, or an alternative heat-resistant, non toxic, soft and malleable yet firm substance. The tubular ring can then be rinsed and autoclaved after use, and reused several times in the same way as the laryngeal mask airway is reused, until deemed to be at the end of its natural life due to wear and tear or until it has been used as many times as deemed the maximal advisable number of times by the manufacturer, taking into consideration the estimated life span of the materials used in its construction.

3: A tubular ring as claimed in claim 1, made of a disposable material, the whole of which is discarded after a single use.

4: A tubular ring, as described in claim 1, in which the innermost wall,ie, that of the smaller circumference/diameter, which lies directly adjacent to and in contact with the LMA or ETT, is made of a hard substance such as hard, non crushable plastic (in a disposable model) or thick, non crushable rubber (in an autoclavable model), while the overlying substance of the ring is made of a softer, more malleable substance such as a gel-like material .

Application No: GB 0006638.1 **Examiner:** Susan Chalmers (Mrs)
Claims searched: 1-4 **Date of search:** 27 April 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

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

UK Cl (Ed.R): A5R: RGEX

Int Cl (Ed.7): A61M: 16/04

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 1017515	(ERICKSON) see bite block 12 in Figures 1 and 4 and page 2 lines 87-111	1,3
X	US 5862801	(WELLS) see the Figures, column 2 lines 36-46 and column 3 line 31 to column 4 line 13	1-4
X	US 5699787	(THOMPSON) see bite block 14, 156 and 210 in the Figures, column 3 line 64 to column 4 line 4 and column 5 line 6 to column 7 line 28	1,3
X	US 5590643	(FLAM) see sleeve 20 and bite block 30 in the figures and column 5 line 6 to page 7 line 21	1-4
X	US 5009227	(NIEUWSTAD) see ring 20 in Figure 1 and column 3 line 67 to page 4 line 4	1,3
X	US 4640273	(GREENE) see the Figures and column 2 line 47 to column 3 line 32	1-4
X	US 4344428	(SHERMAN) see device 1 in the Figures, column 2 line 66 to column 3 line 24 and column 3 line 62 to column 4 line 40	1,3

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.

Application No: GB 0006638.1 **Examiner:** Susan Chalmers (Mrs)
Claims searched: 1-4 **Date of search:** 27 April 2000

Category	Identity of document and relevant passage		Relevant to claims
X	US 4166467	(ABRAMSON) see bite block 40 in the Figures and column 2 line 52 to column 4 line 4	1,3
X	JP 10024043 A	(FUJI) see WPI Abstract Acc No 1998-152931 and JAPIO (PAJ) Abstract	1,3

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.