NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Buyers' guide

Laryngeal masks

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Informing procurement - Encouraging innovation

Contents

Airway devices

Adequate oxygenation is vital for the patient during anaesthesia, intensive care and emergency medicine. Failure to provide adequate oxygenation can result in severe hypoxia, leading to morbidity and mortality within a few minutes.

Oxygen can be delivered to the patient using a facemask but great skill is required to deliver sufficient volumes of gas from the reservoir bag whilst maintaining an adequate seal between the facemask and patient's face. Alternatively, an airway device is commonly placed in the patient to allow oxygen-enriched gases, with anaesthetic gases if required, to be delivered safely to the patient's lungs.

A tracheal tube provides a well established and effective technique of ensuring a patent airway. The end of this tube lies in the trachea and a cuff on the tube can be inflated to produce a seal against the inner wall of the trachea to enable ventilation and prevent the passage of stomach contents into the lower airways. However, passing a tracheal tube through the vocal cords can cause trauma and correct placement of a tracheal tube requires considerable skill and experience.

Laryngeal masks

The laryngeal mask (LM) is an example of a newer type of device. It is much easier to insert than a tracheal tube, causes less irritation and coughing, and the risk of damaging the vocal cords is reduced. Providing ventilation through an LM is much easier than using a facemask. The LM is particularly popular for use in day case surgery. It is also recommended as a rescue device when intubation and ventilation have failed.

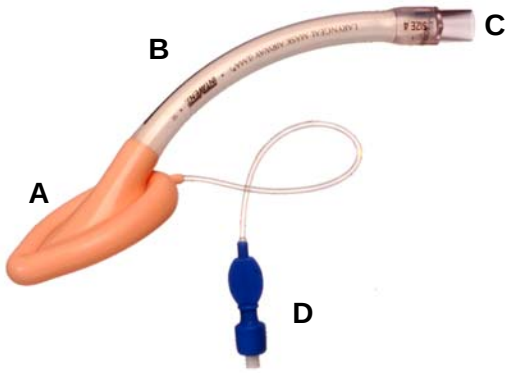


Figure 1. An example of a laryngeal mask
A: inflatable cuff attached to the bowl; B: tube; C: 15 mm male connector; D: pilot balloon with Luer-connector.

The laryngeal mask consists of a tube with an inflatable cuff (Figure 1) that is inserted into the pharynx and sits snugly over the top of the larynx with the tip of the cuff in the entrance to the oesophagus. When the cuff is inflated, a low-pressure seal is formed around the laryngeal inlet enabling spontaneous breathing and gentle positive-pressure ventilation. This type of device is therefore termed a "supraglottic" or "supralaryngeal" airway as it is not passed through the vocal cords.

National guidance

Specific advice on the purchase, maintenance and replacement of anaesthetic-related equipment has been published by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) [1]. Further details are provided in the Purchasing section (page 18).

The Medicines and Healthcare products Regulatory Agency (MHRA) provides general guidance on the purchasing, deployment, maintenance, repair and disposal of medical devices [2] and specific guidance on sterilisation, disinfection and cleaning of reusable medical equipment [3], which was developed by the Microbiology Advisory Committee to the Department of Health.

Several key professional organisations have provided guidance relevant for the use of laryngeal masks including:

- Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines [4,5]
- Royal College of Anaesthetists' (RCoA) guidance [6,7]
- Department of Health statement to RCoA [8]
- Difficult Airway Society (DAS), which has published guidelines on the management of the unanticipated difficult intubation [9].

Project scope

This buyers' guide provides an overview of the currently available laryngeal masks to inform procurement decision making (see Appendix 1 for a current list of products and suppliers). Samples provided for evaluation by UK suppliers between February and May 2007 were tested in the laboratory (see Appendix 2). All masks tested are CE marked indicating that the manufacturer has satisfied the requirements of the EU Medical Devices Directive [10]. Clinical evidence on the performance of the devices was obtained from published trials (see Appendices 3 and 4).

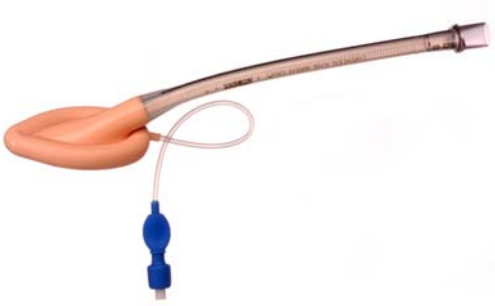
Technical, operational, economic and purchasing considerations are also discussed.

Information about relevant product features and evaluation results are tabulated in the Market Review section and summarise:

- product features that can influence clinical choice
- results of technical assessment tests, which can help to identify products that may perform poorly when used in patients
- whether the product has been evaluated clinically
- cost information.

The original laryngeal mask was invented by Dr Archie Brain in 1983 [11], launched in the UK in 1988 [12] and is called the classic LMA®. This model of standard laryngeal mask is reusable, being made from silicone and intended for up to 40 patients by cleaning and sterilising after use.

Reusable LMs are now available from a number of different manufacturers following the expiry of the original LMA® patent in 2003.



A flexible (reinforced / armoured) laryngeal mask (fLM) suitable for ENT and dental surgery was first introduced in 1990 [13] and called the Flexible LMA® (Figure 2). Compared with standard LMs the tube of a flexible LM is elongated, narrow and usually has an integrated metal coil which enables it to be flexed to allow access to the surgical site whilst preventing tube obstruction.

Figure 2. Flexible LMA®.

A laryngeal mask specifically designed for guiding endotracheal intubation was launched in 1997 [14] and called the intubating LMA® (iLMA). It is designed for use in unanticipated difficult intubations, failed intubations and for patients with limited head/neck movement. The iLMA has a rigid silicone-coated, anatomically curved steel airway tube which closely follows the curvature of the palate and posterior pharynx. The distal end features an epiglottis-elevating bar to lift the epiglottis and allows passage of a tracheal tube or fibreoptic laryngoscope. This type of device is not included in the market survey of this buyers' guide.

The first single-use laryngeal mask was introduced in 1997 and called the LMA Unique® [15]. This has essentially the same design as the reusable classic LMA® but is made of polyvinyl chloride (PVC) which is cheaper to manufacture but cannot withstand autoclaving. A range of single-use LMs are now available from several manufacturers and may be made from either silicone or PVC or a combination of the two materials, for example a silicone cuff and a PVC tube.

The first product from another manufacturer was the Portex SoftSeal launched in 2003 [16].

More recent designs of laryngeal masks incorporate several key innovations.

In 2000 a laryngeal mask was developed which incorporates an integral tube to reduce the risk of air building up in the stomach, and through which stomach contents can be aspirated [17]. This was called the Pro-Seal LMA® (Figure 3) and other design changes were made to improve the seal for positive pressure ventilation.

Figure 3. ProSeal LMA®.

The Ambu AuraOnce LM is an example of one of the newer laryngeal masks [18]. It was launched in 2004 (Figure 4). It differs from other LMs in that the curve of the tube is more pronounced.

Figure 4. Ambu AuraOnce.

There are now several other types of supraglottic airways available on the market, a number having innovative features, although currently most of these products have a relatively small market share.

By replacing the inflatable cuff with gel-like material shaped to provide an adequate seal the i-gel (Figure 5) provides an alternative design [19]. This product also incorporates an integral tube through which stomach contents can be aspirated, if required and to enable the release gas from the patient's stomach.

Figure 5. Intersurgical i-gel.

Published clinical trials and reviews

Over 2500 clinical research papers have studied the original design of laryngeal mask, the classic LMA® [20]. Considerably fewer studies have clinically evaluated other LM devices and these usually provide lower levels of evidence than randomised controlled trails (RCTs) (Appendix 3, Table 6). For many products there is no published clinical data. Table 1 summarises the findings of key prospective trials and review articles.

Eighteen RCTs comparing different laryngeal masks of the same type (standard or flexible) were identified in a literature search conducted in January 2008 [15, 16, 21-36]. Critical analysis of these RCTs has specifically focussed on the five primary outcome measures described in Appendix 3: Results of each individual RCT and limitations in the study design are detailed in Table 7 (Appendix 4). General conclusions from these RCTs and prospective studies listed in Table 1 are summarised in this section.

The reusable classic LMA® is a well-established device and is generally considered to be better than a facemask or tracheal tube [37]. It is suitable for use with spontaneously breathing and mechanically ventilated adults [38] and children [39] for routine elective surgical procedures. The main advantages are that it is quick and easy to insert, has a high insertion success rate and provides a reliable airway [38, 39]. Inadvertent oesophageal placement is avoided but gas leakage can occur at high inflation pressures. It is not designed to completely block access to the oesophagus so air can be inadvertently introduced into the stomach and gastric contents may regurgitate into the trachea [40]. In addition intra-cuff pressure can increase during nitrous oxide anaesthesia [40].

The ProSeal LMA® was designed to improve the seal pressure and reduce the risk of inadvertent inflation of the stomach. Prospective studies and RCTs have confirmed this [41]. It is also easy to insert with a high insertion success rate in both adults [42] and children [43].

The LMA-Unique® has been compared with classic LMA® [15, 21, 22] and Portex SoftSeal [22-26]. The LMA-Unique® was similar in efficacy to the classic LMA® [15, 21, 22], the main difference being the smaller increase in intra-cuff pressure during nitrous oxide anaesthesia for the LMA-Unique® [21]. Several studies report that the LMA-Unique® is easier to insert and causes less trauma than the Portex SoftSeal [22-26].

The Portex SoftSeal LM was the first competitor product to the two LMAs manufactured by Intavent. In most studies the Portex SoftSeal was found to have similar efficacy to the classic LMA® [16, 22, 27-30, 32][1] although one study suggested that the stiffer tube and cuff may lead to an increase in the incidence of trauma [27]. Intra-cuff pressure was generally more stable than with the classic LMA® [15, 27-32] as the SoftSeal is made from PVC. When compared to the LMA-Unique®, the SoftSeal is more difficult to insert with a greater risk of causing trauma [22-26].

[1] Two studies by van Zundert [16, 28] were on the same group of patients with the same results; the second study was therefore not included in Appendix 4, Table 7, but is included in the list of references for further information.

Table 1 – Summary of key prospective studies and review papers on specific laryngeal masks

Reference	Methods	Results	Authors' summary conclusion
Classic LMA			
Asai and Morris, 1994 [40]	Review article with 265 references	Extensive review article discussing the advantages and disadvantages of the device	
Verghese and Brimacombe, 1995 [38]	Prospective consecutive series of 11,910 patients	During a two-year survey in two hospitals, Classic LMAs were used in 30% of patients, 44% of which received positive-pressure ventilation. Placement was successful in 99.81% of patients; when not successful (23 patients) a tracheal tube was used. 18 critical incidents occurred related to the airway	The Classic LMA is safe and effective for both spontaneous and controlled ventilation
Brimacombe, 1995 [37]	Meta-analysis of 52 published studies comparing Classic LMA with facemask and tracheal tube	Only disadvantages of the classic LMA compared to the tracheal tube were that it had a lower sealing pressure and a greater frequency of gastric insufflation; the only disadvantage compared to the facemask was that oesophageal reflux was more likely	The LMA has several advantages over the tracheal tube and facemask and a few disadvantages
Lopez-Gil *et al*, 1996 [39]	Prospective series of 1400 paediatric patients. Sizes used:1, 2, 2.5, 3 and 4	First attempt insertion success rate 90%; 2% required an alternative method of insertion; overall problem rate was 11.5% - most problems were related to the use of the size 1 LM	The classic LMA provides a safe and effective form of airway management for infants and children for both spontaneous and controlled ventilation
ProSeal LMA			
Cook *et al*, 2005 [41]	Literature review of 59 RCTs or other clinical studies and 79 other publications	Compared to the Classic LMA, insertion with ProSeal takes a few seconds longer; first attempt success rate is lower, but overall insertion success rate is equivalent; the airway seal is improved by 50%; the integral tube enables early diagnosis of mask misplacement and allows gastric drainage	The ProSeal offers significant benefits over both the Classic LMA and the tracheal tube
Wheeler, 2006 [43]	Prospective series of 120 children. Sizes used: 1.5, 2, 2.5 and 3	First attempt insertion success rate 94%; overall insertion success rate for ProSeal and gastric tube was 100%	Useful alternative to tracheal intubation in children due to the higher leak pressure and the ability to evacuate fluid and air from the stomach
Cook and Gibbison, 2007 [42]	Prospective consecutive series of 1000 cases	First attempt insertion success rate 85%; overall insertion success rate 99.4%; mean insertion time was 12 s; mean airway seal was 32 cmH_2O; blood visible on 8% of devices	The ProSeal has a high success rate, high levels of clinical utility and low rates of complications
Portex SoftSeal			
Orlikowski, 2004 [44]	Prospective series of 400 patients. Sizes used: 3, 4 and 5	First attempt insertion success rate 83.8%; in 15 (3.8%) the device could not be placed, in 12 of these a Classic LMA could be placed; blood visible on 12.2% of devices. 22 out of 29 anaesthetists considered it inferior to the classic LMA	The authors considered that the SoftSeal was not a suitable alternative to the Classic LMA in its (then) present configuration

Table 1 – Summary of key prospective studies and review papers on specific laryngeal masks

Reference	Methods	Results	Authors' summary conclusion
Ambu LM			
Hagberg *et al*, 2005 [18]	Prospective series of 118 non-paralysed anaesthetised ASA I-II patients. Sizes used: 3, 4 and 5	First attempt insertion success rate 92.4%, 100% insertion success after one or two attempts; adequate ventilation in all patients; vocal cords could be visualised by fibrescopic endoscopy in 91.5% of patients; oropharyngeal leak pressure was 24 cmH_2O; blood detected on device in 8.5% of patients	The Ambu LM is a reliable and well tolerated single-use supraglottic airway
I-gel			
Gabbott and Beringer, 2007 [45]	Prospective series of 100 adult patients. Sizes used: 4	Insertion success rate on first or second attempt 98%; mean leak pressure 24 cmH_2O; blood on one device only	

The Ambu AuraOnce has been studied in too few patients (180 patients in 4 studies - see Appendix 3) to draw strong conclusions but in the studies to date the Ambu LM has been found to be generally similar in efficacy to the classic LMA®, but is easier to insert [33-35]. However, one study suggested that more manipulation is required to maintain an effective airway with the Ambu AuraOnce [35]. Another small study reported the Ambu LM as similar in efficacy to the LMA-Unique® and the Portex SoftSeal, although it was quicker to insert than the other two it had less failures than the SoftSeal and more than the LMA Unique® [32]. Possibly both the improved ease of insertion and the difficulties with maintaining an airway may both be related to its increased tube curvature.

Reusable and single-use flexible LMs were compared in one RCT [36]. Both devices had similar clinical efficacies during anaesthesia for dental surgery in children aged 2 to 12 years.

Material of construction

Reusable LMs are made from medical grade silicone rubber. Single-use laryngeal masks are usually made from either medical grade silicone or medical grade polyvinyl chloride (PVC) or both, for example, the tube being made from PVC and a cuff made from silicone. Some devices are made from a gel-like thermoplastic elastomer (TPE), eg. Intersurgical i-gel.

Flexible laryngeal masks incorporate a metal wire coiled into the tube to prevent the tube collapsing when it is flexed to allow the surgeon access to the operative site.

Generally, cuffs made from silicone are softer and less sticky than those made from PVC. PVC tubes tend to be more rigid [15]. Autoclaving is not possible with devices made from PVC or TPE so they are available as single-use items only. Laryngeal masks made from silicone are available as either single-use or multiple-use items and tend to be more expensive than those made from PVC.

MRI compatibility

The one-way valve that provides a seal when the cuff is inflated commonly has a metal spring, so these must not be used in magnetic resonance imaging (MRI) scanners. However, some manufacturers offer a version with a plastic spring that is suitable for use with MRI scanners. Devices without a cuff do not usually contain metal parts.

Epiglottic bars

The original Classic LMA® has epiglottic bars to avoid the patient's epiglottis falling into the tube and preventing obstruction of the airway (Figure 6). The usefulness of this feature is still debated [46, 47]. The patent for this feature expires during 2008, so currently none of the other laryngeal masks available from other manufacturers have epiglottic bars.

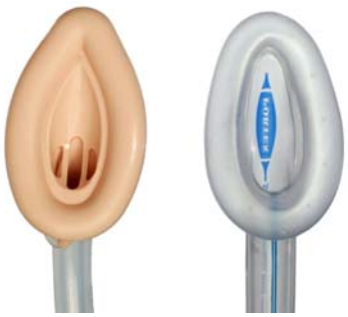


Figure 6. Epiglottic bars on the Classic LMA® (left). Other laryngeal masks, such as the Portex SoftSeal (right) do not have epiglottic bars.

Tube curvature and diameter

Curvature of the tubes on the laryngeal masks and i-gel are similar except for the AuraOnce and Aura40 laryngeal masks supplied by Ambu which have a curvature close to 70°, intended by the manufacturer to aid insertion of this device into the patient[2].

Diameter of the tubes varied. In particular, the tube diameter in flexible (reinforced) laryngeal masks is narrower, which can increase the resistance to gas flow in these devices.

Effect of nitrous oxide on cuff pressure

Nitrous oxide is sometimes given during anaesthesia to both reduce the amount of other anaesthetics required and also to provide some pain relief. Studies have demonstrated that nitrous oxide diffuses across the material of the cuff, so that during prolonged surgery, the volume of the gas in the cuff, and hence the pressure, increases [28, 48]. This effect is more pronounced with silicone than PVC material. Levels of nitrous oxide in theatres are limited by the Control of Substances Harmful to Health (COSHH) regulations. As nitrous oxide is a greenhouse gas its use is starting to be questioned although recent surveys report that the majority of anaesthetists continue to use it in their paediatric [49] and adult [50] practice and less than 5% thought that its use should be restricted.

[2] Ambu now also market the AuraStraight laryngeal mask for those who prefer the more ‘traditional' shape.

Types of laryngeal mask

The standard LM is appropriate for use in most routine elective surgical procedures. During elective surgery standard LMs should be used only with fasted patients and those who do not have other significant risk factors for regurgitation as they do not prevent gastric contents entering the trachea. In cases of mildly increased risk the use of devices designed to increase safety are appropriate. In emergencies, when stomach contents of the patient are not known, and when intubation has failed it may be more appropriate to use devices with integral gastric tubes, eg ProSeal [41] or i-gel, to reduce the risk or aspiration of gastric contents. Flexible (reinforced) laryngeal masks are particularly useful for surgical procedures in the neck, such as adenotonsillectomy and dental surgery, as they have wire incorporated into the tube to prevent occlusion when the tube is bent to avoid the surgical field.

Single-use vs reusable

Laryngeal masks are commonly blood-stained when removed from the patient [51] and routine methods of cleaning laryngeal masks do not completely remove protein deposits [52-54]. Furthermore, commonly-used methods of sterilisation do not denature prions [55], such as those linked to the transmission of the fatal disease new variant Creutzfeldt-Jakob disease (vCJD).

Both standard and flexible laryngeal masks are now available as reusable or single-use products. Single-use devices reduce the possibility of transmission of infectious material from one patient to another [14]. Although reusable LMs may be used in up to 40 or 50 patients there are no documented cases of cross-infection occurring through the use of reusable laryngeal masks.

Guidelines published by the Royal College of Anaesthetists (RCoA) and AAGBI both encourage the use of single use devices, to reduce the possibility of the transmission of prions and other infectious material from one patient to another [4-8] The AAGBI also advise that "the balance between single-use as against reusable equipment will require local determination based on risk assessment of patients safety, available facilities and cost" [4].

Tonsillectomy and adenoidectomy are considered by NICE (National Institute for Health and Clinical Excellence) to be medium-risk procedures for the transmission of vCJD in its guidance on the use of surgical instruments [56]. Laryngeal masks can come into close contact with tonsils, potential sources of the prions linked to the transmission of this fatal disease. Current RCoA and AAGBI guidelines for anaesthetising patients for tonsillectomy are that all anaesthetic equipment placed in the mouth or respiratory tract should be single-use disposable and LMs should be destroyed after use for tonsillectomy [4-8]. This primarily affects the selection of flexible LMs which are designed for ENT and dental surgery (see page 5)

Differences in design and material characteristics can alter the performance of laryngeal masks during clinical use. Although new AAGBI guidance (currently in draft) continues to recommend single-use LMs, it recognises that "the reusable design is in common use and many anaesthetists perceive it as being less traumatic" [5].

In practice there is significant use of both types of standard laryngeal masks. A recent survey of 148 NHS Acute Hospital Trusts in England (September, 2006) demonstrated that reusable LMs continue to be used [57]. All operating theatre departments who responded (response rate of 87%) reported they stocked single-use LMs and 69% of routinely used them. However, most also stocked reusable LMs (82%) usually because of cost factors and user preference. Review of market information from a key distributor to NHS Trusts indicates that reusable products could be used for up to 40% of procedures (Table 2). However the proportion of reusable LMs through this supplier may increase in the future as the classic LMA® has only recently been added to their catalogue.

Table 2. Numbers of laryngeal masks purchased from NHS Supply Chain

Type of laryngeal mask	Number of products bought	
	2006/07	2007/08
Single-use standard	357,520	427,330
Reusable standard	5,828	7,067
# of patients assuming 40 uses	233,120	282,680
Single-use flexible	14,620	26,330
Reusable flexible	No product available via NHS Supply chain	

Cleaning and sterilisation of multiple-use laryngeal masks

General advice on cleaning and sterilising of medical devices is available from the Medicines and Healthcare products Regulatory Agency (MHRA) [3].

It is vital to adhere to manufacturer's instructions for cleaning and sterilising specific laryngeal masks and local policies, developed by the Trust Infection Control Committee to ensure compliance with relevant national standards. It is important that the nominated consultant anaesthetist for procuring equipment liaises with the designated microbiologist and Infection Control Team to obtain advice on decontamination and sterilisation and ensures the agreed practice is monitored for compliance.

Laryngeal masks used during tonsillectomy and adenoidectomy must be discarded after use and must not be reprocessed [6-8].

Due to the risk of cross-contamination between devices when cleaned in batches, one study has suggested that multiple-use laryngeal masks should be cleaned in isolation [58]. Supplementary cleaning of reusable LMs, including soaking in potassium permanganate, has been shown to dramatically reduce protein deposits [59] and its use is being considered in Australasia.

Choosing the correct size

Laryngeal masks are available in a range of up to eight sizes for use in neonates up to large adults. The size of classic LMA® which is recommended for use with particular patients has changed over time [60]. The current recommendations are summarised in Table 3. In general, it is recommended that LM sizes 4 and 5 are used with female and male adult patients, respectively. Sizing for the i-gel is different and three sizes are currently available, none being suitable for children (Table 4).

Some manufacturers colour-code the different sizes to improve identification of the correct product.

Table 3. Manufacturers' recommended size for laryngeal masks is linked to patient's weight.

Laryngeal mask size	Patient weight (kg)
1	neonates up to 5
1.5	infants 5 to 10
2	children 10 to 20
2.5	children 20 to 30
3	patients 30 to 50
4	patients 50 to 70
5	patients 70 to 100
6	patients > 100

Table 4. Manufacturers' recommended size of the i-gel for particular weights of patients.

i-gel size	Patient weight (kg)
3	30 to 60
4	50 to 90
5	> 90

Ease of breathing through breathing system components

Careful selection of appropriate devices could markedly reduce the work of breathing for patients. A high resistance to gas flow increases the work of breathing for the patient and may also affect the triggering of some ventilators. During anaesthesia with a laryngeal mask several components, including a breathing system filter, may be connected in sequence to the anaesthetic machine. The total resistance to gas flow experienced by the patient is the sum of resistances in each individual device and any additional restriction due to poor alignment of the laryngeal mask with the larynx [61-63].

The resistance to air flow is measured as the pressure drop at a particular flow. For this evaluation the pressure drop across laryngeal masks was measured with the tube in the normal shape and also when flexed to mimic their shape in a patient (see Appendix 2 for further details). Pressure drop is tabulated in the Market Review in units of pascal (Pa), where 100 Pa ≈ 1.02 cmH_2O.

Pressure drop across LMs is similar to that across breathing systems and breathing system filters [59-60]. We found a fourfold difference in pressure drop for LMs designed for the same purpose (results range from 48 to 216 Pa in 'standard' size 4 single-use LMs tested). Previously a five fold difference for breathing system tubing intended for adults (62 to 329 Pa) has been reported [64] and a fivefold difference for breathing system filters [65][3]. The overall resistance to gas flow experienced by the patient is the resistance of each breathing component added together.

Resistance is less through standard LMs than through tracheal tubes, as the diameter of the tube in a standard LM is greater. Although the pressure drop across the classic LMA® is high, compared with other LMs; there is no clinical evidence that this causes any adverse effects on patients.

In clinical practice the resistance experienced by the patient *in situ* will also depend on how well aligned the laryngeal mask is with the larynx and the resistance within the devices [64-66]. Although technical data can enable careful selection of each component in the breathing circuit, to reduce the overall resistance, if the LM shape and construction impede correct positioning then this will dominate. Clearly clinical evaluation is required to investigate this last factor.

Connection to other breathing system components

Disconnections are a relatively common, life-threatening occurrence, which can be caused by incorrectly dimensioned connectors between different components of the breathing system [67-69]. Even if the connectors on the components are correctly sized a secure connection between a laryngeal mask and the breathing system is only made if the correct 'push and twist' technique is used, with the appropriate force and rotation. For further information see Appendix 2.

Flexibility

A laryngeal mask with a more rigid tube may be easier to insert into the throat of a patient although it may cause more trauma during insertion. A more flexible tube may allow movement of the tube during manipulation of the breathing system, for example, without causing the cuff to move. Thus, depending on the use of the laryngeal mask, either a more rigid or a more flexible tube may be advantageous. Flexibility of the laryngeal masks has been measured and they have been designated as very flexible, flexible, rigid and very rigid

[3] The flows are specified in the appropriate standards for breathing system tubing and breathing system filters.

in the Market Review Tables based on the criteria outlined in Appendix 2. Laryngeal masks marketed as 'flexible' were all 'very flexible' when assessed using this criteria. Devices are available to help insertion of flexible LMs [66].

Inflation of the cuff

Laryngeal masks are labelled with the recommended maximum volume to be used when inflating the cuff, however cuff inflation should be gradual and stopped as soon as an adequate seal has been achieved. Indiscriminate inflation to the maximum volume can cause trauma. Manometers are available to measure the pressure in the cuff so the anaesthetist can obtain the optimum inflation volume. The maximum volume stated by manufacturers can differ significantly, even for the same LM size. For example, the maximum volume recommended for cuff inflation of the size 4 version of the classic LMA® and Portex SoftSeal is 30 ml and 35 ml, respectively.

Use of laryngeal masks for airway management

Guidelines on the management of the unanticipated difficult intubation have been published by the Difficult Airway Society [9]. DAS recommends that a tracheal tube can be passed through a laryngeal mask into the patient's trachea under fibreoptic guidance if the initial tracheal intubation has failed. However, DAS recognised that there are some limitations to the use of the classic LMA® as a conduit for tracheal intubation. The tube diameter of some products more recently placed on the market can be larger than the classic LMA®, which may facilitate passage of a larger diameter tracheal tube [16]. However, other factors may make the passage of a tracheal tube through some other laryngeal masks more difficult [70], for example, the increased curvature of the tube, such as found in the Ambu laryngeal mask, is reported to make this more difficult [71].

DAS also recommends the use of an LM as a rescue device in the "can't intubate, can't ventilate" scenario.

When these guidelines were published the classic LMA® was the only model available. However, at present there is inadequate evidence to support changing from the cLMA to other devices for these emergency and rescue uses.

Single-use versus multiple-use devices

Single-use laryngeal masks are supplied sterile ready for immediate use. Most multiple-use laryngeal masks are supplied clean and require autoclaving before first use, although multiple-use products supplied by Flexicare and ProAct are supplied sterile.

The suppliers of most multiple-use laryngeal masks recommend that the devices can be used in 40 patients, although Marshall Products warrantees that the 550 LAD can be used for 50 patients. If the cost of reprocessing a multiple-use laryngeal mask is assumed to be £1.05 [72] and a multiple-use device costing £40 is used for 40 patients, then the cost per patient, including reprocessing, is £2, which is cheaper than the list price of single-use devices. However further indirect costs should be considered when evaluating the overall cost of a laryngeal mask. For multiple-use versions, there are cost implications from needing additional laryngeal masks to use when other masks are being reprocessed, therefore cost per patient should also cover the downtime. Administrative costs for preparation and receiving of reprocessed masks should also be considered.

Storage space required for single-use devices also needs to be considered, depending on frequency of delivery and stock levels. The cost of disposal of single-use devices, usually priced on weight, should be taken into account when comparing the overall cost of single-use and multiple-use devices.

In a recent survey [58], many Trusts were using multiple-use laryngeal masks primarily because of cost effectiveness, in addition to user preference.

Clinical evidence

As laryngeal masks are used in critical patient care scenarios it is important to follow the guidelines from MHRA on procuring the most appropriate device [2]. AAGBI guidelines on purchasing anaesthetic equipment [1] recommend that a nominated consultant anaesthetist with responsibility for purchasing decisions of anaesthetic equipment is fully involved in the selection process and that the reasons for equipment choice be recorded.

Choosing which laryngeal mask to purchase for particular groups of patient should be based on evidence of clinical effectiveness. Ideally published randomised controlled trials (RCTs) will have already demonstrated the clinical effectiveness of the product, as these usually provide a higher level of evidence than a prospective case series (see Appendix 3). Published RCTs comparing products listed in the Market Survey are detailed in Appendix 4 (Table 7) and summarised in the clinical evidence review section on page 7. Currently, published RCTs are not available for most LMs in this buyers' guide and so clinical evidence of their suitability is unavailable. Ongoing studies can be found on the National Research Register (www.nrr.nhs.uk), currently being moved to the UK Clinical Research Network Portfolio Database (pfsearch.ukcrn.org.uk).

Sustainable procurement

The UK Government launched its current strategy for sustainable development, Securing the Future [74-76], in March 2005 and describes four priorities to progress sustainable development, in the UK and worldwide. Within the NHS PASA Sustainable Development Policy [77] hospitals are encouraged to:

- prevent pollution
- promote resource efficiency and use of renewable resources
- apply waste hierarchy principles (reduce, reuse, recycle, recover)
- rise to the challenge of addressing climate change.

Procurement of laryngeal masks has an influence across all of these areas.

The laryngeal mask was originally manufactured in the UK and could be used for up to 40 patients. Most laryngeal masks are now manufactured in the Far East. With the availability of single-use devices, up to 40 times the number of laryngeal masks are now shipped from the Far East to the UK for use in anaesthesia. Each of these single-use devices then has to be disposed of and treated as clinical waste.

Products designed for low cost decontamination to extend serviceable life are preferable from a sustainability point of view. Use of multiple-use laryngeal masks can reduce transport and storage requirements, the use of raw materials, as well as incineration and disposal costs.

Service quality

Other factors to consider when assessing manufacturers and suppliers of medical devices are their quality systems, references from existing users, historical contract performance, stock levels and training, education and support they provide.

This market review summarises the product details, results of technical testing and indicates the presence of any published clinical evidence for the majority of laryngeal masks available for purchase in the UK in February 2007. Other manufacturers and products have come on to the market since that time and so a summary of laryngeal masks currently available in the UK is included in Appendix 1 (Table 5).

Twelve manufacturers (Appendix 1) originally chose to be involved in this study and supplied a total of 31 different products for evaluation. These consisted of the following:

Single-use 'standard' laryngeal mask	14
Single-use 'flexible' (reinforced / armoured) laryngeal mask	6
Multiple-use 'standard' laryngeal mask	7
Multiple-use 'flexible' (reinforced / armoured) laryngeal mask	2
Other devices (ProSeal LMA® and i-gel)	2

The two 'Other devices' differ from other laryngeal masks supplied in that both incorporate an integral tube designed to allow stomach contents to be aspirated, if required. In addition, the Intersurgical i-gel does not have an inflatable cuff as it relies on the shape and flexibility of the thermoplastic elastomer to provide an effective seal.

For each product samples of size 2 and size 4 laryngeal masks (or their equivalent based on patient weights) were supplied for assessment (see also Tables 3 and 4).

Many other supraglottic airways are available, but have not been included in this buyers' guide: the i-gel and ProSeal were included as this was requested by stakeholders. Other supraglottic airways may be more appropriate than a laryngeal mask in particular situations. Following the assessment, manufacturers may have changed or improved the design and performance of their products. Manufacturers or suppliers should be contacted to obtain information on currently-available products.

The evaluation of each model included a technical assessment (see Appendix 2) of:

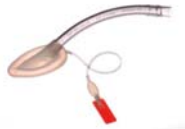
- resistance to flow through the laryngeal mask (pressure drop)
- whether the 15 mm male connector was correctly sized
- measurement of flexibility
- whether the multiple-use devices could withstand the number of simulated uses as recommended by the manufacturer (including resterilisation).

The first two assessments were taken from the draft standard for supralaryngeal airways [71].

How to use the market review tables

		Notation Used	Location of further info
Features	**Sizes available**	Different sizes are available for use with patients of various weights. See Tables 3 & 4	**Page 14**
	Number in pack	Number of devices in pack as supplied	
	Material	Laryngeal masks are made from either polyvinyl chloride (PVC) or silicone. Manufacturers were requested to supply details of the materials used in their laryngeal masks	**Page 10**
	Clean / sterile	Sterile EO - sterilised with ethylene oxide; Sterile R - sterilised with radiation; Clean - supplied clinically clean	**Pages 13**
	Weight (g) (size 4)	Weight of unpackaged size 4 device. The weight of other sizes of device will be different	
	Number of reuses	Manufacturer's recommended number of reuses	**Page 41**
Evaluation	**Sizes tested**	Manufacturers were requested to supply sizes 2 and 4 for evaluation, but some supplied other sizes	
	Pressure drop	This is an indication of the potential ease of breathing	**Pages 14, 40**
	Unflexed	Pressure drop measured with device as removed from packaging	**Pages 14, 40**
	Increase when flexed	Increase in pressure drop measured with device placed in template to simulate clinical use as a percentage	**Pages 14, 40**
	Flexibility	The force required to maintain the laryngeal mask with a bend of 90° was recorded. The force was rated as follows: 0 to 1 N — very flexible (v. flex) >1 to 2 N — flexible >2 to 3 N — rigid >3 N — very rigid (v. rigid)	**Pages 15, 41**
	Withstand reuse?	✓ - able to withstand recommended number of reuses ✗ - unable to withstand recommended number of reuses	**Page 41**
	Connector	✓ - indicates 15 mm male connector is correctly sized ✗ - indicates 15 mm male connector is not correctly sized	**Pages 15, 41**
	Comparative RCT?	✓ - Randomised Controlled Trials have been published	**Pages 7-9, 45-53**
	Individual list price (£)	Manufacturers list price per laryngeal mask excluding VAT *Discounts may be available when purchasing large numbers of laryngeal masks*	

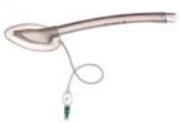
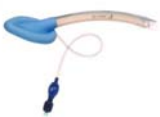
Market review

	Single-use standard	Ambu AuraOnce		Armstrong Medical LaPremiere		Flexicare Medical LarySeal Blue [4]		Flexicare Medical LarySeal Clear [4]		Intavent Orthofix LMA Unique		Intersurgical Solus		Marshall Products Silicone LAD	
															
Features	**Sizes available**	1 to 6		1 to 2.5	3 to 5	1 to 5		1 to 5		1 to 5		1 to 5		1 to 2.5	3 to 5
	Number in pack	10		25	50	10		10		10		20		10	20
	Material	Silicone & PVC		Silicone & k-resin		Silicone		PVC		PVC		PVC		Silicone	
	Clean / sterile	Sterile R		Sterile EO		Sterile EO		Sterile EO		Sterile EO		Sterile EO		Sterile EO	
	Weight (g) (size 4)	44		46		47		46		42		31		46	
Evaluation	**Sizes tested**	2	4	2	4	2	4	2	4	2	4	2	4	2	4
	Pressure drop														
	Unflexed (Pa)	61	70	183	147	235	216	122	119	195	159	135	148	194	133
	Increase when flexed	13%	9%	10%	9%	22%	9%	17%	11%	12%	12%	13%	10%	9%	9%
	Flexibility	v. flex	flexible	flexible	v. flex	flexible	flexible	rigid [5]	rigid [5]	flexible	flexible	flexible	flexible	flexible	flexible
	Connector	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Comparative RCT ?		✓								✓				
	Individual list price (£)	3.35		5.95		5.80		4.00		8.95		8.00		4.10	

[4] Manufacturer comment: LarySeal products now have colour coded pilot balloons and offer a colour coded cuff inflator to simplify inflation of the cuff to the correct volume.

[5] Manufacturer comment: PVC tube softness has been changed since the testing for this report, to make it more pliable.

Market review

	Single-use standard	Marshall Products Clearview LAD		Meditech Systems Laryngeal Mask [6]		ProAct Medical Pro-Breathe PVC		ProAct Medical Pro-Breathe Silicone		Smiths Medical Portex SoftSeal		Teleflex Medical Crystal Airway Mask		Vital Signs Vital Seal	
															
Features	**Sizes available**	1 to 5		1 to 5		1 to 5		1 to 5		1 to 5		1 to 5		1 to 5	
	Number in pack	10		10		10		10		10		10		20	
	Material	PVC		Silicone/ polycarbonate		PVC		Silicone		PVC		PVC		PVC	
	Clean / sterile	Sterile EO		Sterile EO		Sterile EO		Sterile EO		Sterile EO		Sterile EO		Sterile EO	
	Weight (g) (size 4)	40		44		43		49		50		44		39	
Evaluation	**Sizes tested**	2	4	2	4	2	4	2	4	2.5	4	2	4	2	4
	Pressure drop														
	Unflexed (Pa)	147	115	210	168	186	132	215	199	52	49	83	48	139	133
	Increase when flexed	13%	12%	11%	12%	22%	13%	12%	11%	38%	20%	38%	36%	9%	11%
	Flexibility	flexible	rigid	flexible	flexible	rigid	v. rigid	not tested		rigid	v. rigid	flexible	flexible	flexible	rigid
	Connector	✓	✓	✗ [7]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Comparative RCT ?										✓				
	Individual list price (£)	2.95		6.50		2.95		4.95		8.49		3.00		6.00	

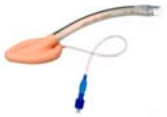
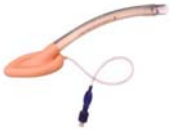
[6] Meditech Systems can supply laryngeal masks with a recording chip, which can be used with a recording / scanning monitor to keep a record of each use.
[7] Manufacturer comment: In response to these results they checked the batches used to supply samples for testing and could not confirm the test results. They therefore state that their products are compliant to this ISO requirement.

Market review

	Single-use flexible	Ambu AuraFlex		Intavent Orthofix Flexible LMA		Intersurgical Solus Flexible		Medis Laryngeal Mask Flexible		ProAct Medical Pro-Breathe PVC	ProAct Medical Pro-Breathe Silicone	
												
Features	**Sizes available**	1 to 5		1 to 5		1 to 5		1 to 5		1 to 5	1 to 5	
	Number in pack	10		10		10		10		1	1	
	Material	Silicone & PVC		PVC		PVC		Silicone		PVC	Silicone	
	Clean / sterile	Sterile R		Sterile EO		Sterile EO		Sterile EO		Sterile EO	Sterile EO	
	Weight (g) (size 4)	35		32		31		41		33	40	
Evaluation	**Sizes tested**	2	4	2	4	2.5	4	2	4	4	2.5	4
	Pressure drop											
	Unflexed (Pa)	484	674	279	417	420	677	601	486	526	628	555
	Increase when flexed	9%	6%	11%	10%	9%	3%	12%	10%	5%	7%	3%
	Flexibility	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex	v. flex
	Connector	✓	✓	✓	✓	✓	✓	✓	✓	✘ [8]	✓	✓
	Comparative RCT ?			✓								
	Individual list price (£)	15.00		30.00		16.00		15.00		9.95	14.95	

[8] Manufacturer comment: In response to these results they immediately implemented a full review of testing for the connector size in order to ensure full compliance. The manufacturer now uses a GO/NOGO gauge to ensure compliance to BS EN ISO 5356-1:2004 on a more frequent sample basis.

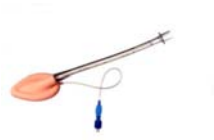
Market review

	Multiple-use standard	Ambu Aura40		Armstrong Medical LaEncore		Flexicare Medical LarySeal Multiple		Intavent Orthofix Classic LMA		Marshall Products 550 LAD		Meditech Systems Laryngeal Mask [6]		ProAct Medical Pro-Breathe Silicone	
															
Features	**Sizes available**	1 to 6		1 to 2.5	3 to 5	1 to 5		1 to 6		1 to 2.5	3 to 5	1 to 5		1 to 5	
	Number in pack	1		10	20	1 or 10		1		10	20	5		10	
	Material	Silicone		Silicone/ polycarbonate		Silicone		Silicone		Silicone		Silicone/ polycarbonate		Silicone	
	Clean / sterile	Non sterile		Clean		Sterile EO		Clean		Clean		Clean		Sterile EO	
	Weight (g) (size 4)	52		46		50		45		47		49		49	
	Number of reuses	40		40		40		40		50		40		40	
Evaluation	**Sizes tested**	2	4	2	4	2	4	2	4	2.5	4	2	4	2	4
	Pressure drop														
	Unflexed (Pa)	59	63	187	142	168	173	229	182	103	140	270	228	212	155
	Increase when flexed	9%	6%	12%	9%	25%	13%	10%	11%	14%	8%	14%	10%	11%	11%
	Flexibility	v. flex	v. flex	flexible	flexible	flexible	flexible	flexible	v. flex	flexible	flexible	v. flex	flexible	flexible	flexible
	Withstand reuse?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Connector	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗ [7]	✓	✗ [8]	✓
	Comparative RCT ?							✓	✓						
	Individual list price (£)	41.00		75.00		37.00		91.00		33.50		65.00		34.95	

[7] Manufacturer comment: In response to these results they checked the batches used to supply samples for testing and could not confirm the test results. They therefore state that their products are compliant to this ISO requirement.

[8] Manufacturer comment: In response to these results they immediately implemented a full review of testing for the connector size in order to ensure full compliance. The manufacturer now uses a GO/NOGO gauge to ensure compliance to BS EN ISO 5356-1:2004 on a more frequent sample basis.

Market review

	Multiple-use flexible	Intavent Orthofix Flexible LMA		Medis Laryngeal Mask Flexible	
					
Features	**Sizes available**	2 to 5		1.5 to 2.5	3 to 5
	Number in pack	1		10	20
	Material	Silicone		Silicone	
	Clean / sterile	Sterile EO		Clean	
	Weight (g) (size 4)	38		42	
	Number of reuses	40		40	
Evaluation	**Sizes tested**	2	4	2	4
	Pressure drop				
	Unflexed (Pa)	580	448	594	537
	Increase when flexed	11%	9%	9%	6%
	Flexibility	v. flex	v. flex	v. flex	v. flex
	Withstand reuse?	✓	✓	✓[9]	✓[9]
	Connector	×[11]	✓	×	✓
	Comparative RCT ?	✓	✓		
	Individual list price (£)	135.00		80.00	

	Other devices	Intersurgical i-gel		Intavent Orthofix ProSeal LMA
				
Features	**Sizes available**	3 to 4	5	1.5 to 5
	Number in pack	25	25	1
	Material	TPE		Silicone
	Clean / sterile	Sterile EO		Clean
	Weight (g) (size 4)	78		63
	Number of reuses	N/A (single-use)		40
Evaluation	**Size tested**	4		4
	Ease of breathing			
	Unflexed (Pa)	53		233
	Increase when flexed	12%		13%
	Flexibility	v. rigid		v. flexible
	Withstand reuse?	N/A (single-use)		×[10]
	Connector	✓		✓
	Comparative RCT ?			✓
	Individual list price (£)	10.00		99.00

[9] Samples were supplied late and were only used 30 times, but withstood this test.
[10] The cuff started to separate from the 'bowl' of the device after 16 cycles in the sample tested.
[11] Correctly dimensioned before the 40 simulated repeated uses, but did not comply when tested afterwards.

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Appendix 1: Supplier and product details

Table 5 – Models and manufacturers of laryngeal masks currently available in the UK

Model	Manufacturer / supplier
Reusable - standard	
550 LAD	Marshall Products
Aura40	Ambu
Classic LMA®	Intavent Orthofix
LaEncore	Armstrong Medical
Laryngeal Mask	Meditech Systems
LarySeal Multiple	Flexicare Medical
ProBreathe Silicone	ProAct Medical
Standard Reusable LM	P3 Medical
Single use - standard	
AuraOnce	Ambu
AuraStraight	Ambu
Clearview LAD	Marshall Products
Crystal Airway mask	Teleflex Medical
Integral Silicone Laryngeal Mask	Fannin UK
LaPremiere	Armstrong Medical
Laryngeal Mask	Meditech Systems
Laryngeal Mask, Economy	P3 Medical
Laryngeal Mask, Silicone	P3 Medical
LarySeal Blue	Flexicare Medical
LarySeal Clear	Flexicare Medical
LarySeal MRI (MRI compatible)	Flexicare Medical
LMA Unique®	Intavent Orthofix
Portex SoftSeal	Smiths Medical
Pro-Breathe PVC	ProAct Medical
Pro-Breathe Silicone	ProAct Medical
Solus	Intersurgical
Silicone LAD	Marshall Products
Vital Seal	Vital Signs

see next page for more products

Appendix 1: Supplier and product details

Table 5 – Models and manufacturers of laryngeal masks currently available in the UK (continued)

Model	Manufacturer / supplier
Reusable - flexible	
Flexible LMA®	Intavent Orthofix
Laryngeal mask flexible	Medis
Laryngeal mask reinforced	P3 Medical
Reusable 550	Marshall Products
Single use - flexible	
AuraFlex	Ambu
Flexible LMA®	Intavent Orthofix
Integral Silicone Laryngeal Mask	Fannin UK
LarySeal Flexi	Flexicare Medical
Laryngeal mask flexible	Medis
Laryngeal mask reinforced	P3 Medical
ProBreathe PVC	ProAct Medical
ProBreathe Silicone	ProAct Medical
Silicone single-use flexible	Marshall Products
Solus flexible	Intersurgical
Visionary	Marshall Products
Reusable - laryngeal masks incorporating integral tube for gastric aspiration	
ProSeal LMA®	Intavent Orthofix
Single-use - laryngeal masks incorporating integral tube for gastric aspiration	
Supreme	Intavent Orthofix
I-gel	Intersurgical

Appendix 1: Supplier and product details 37

New suppliers not included the Market Survey tables are indicated by # , as their products became available in the UK after technical testing was completed.

Supplier	Ambu Limited	Armstrong Medical Ltd.	Fannin UK Limited #
Address	8 Burrel Road St. Ives Cambridgeshire PE27 3LE	Wattstown Business Park Newbridge Road Coleraine BT52 1BS	Unit 2B Pincents Kiln Industrial Estate Calcot Reading RG31 7SB
Telephone	01480 498403	02870 356029	01189 305333
Fax	01480 498405	02870 356875	01189 305111
Website	www.ambu.co.uk	www.armstrongmedical.net	www.fanninuk.com

Supplier	Flexicare Medical Limited	Intavent Orthofix Limited	Intersurgical Limited
Address	Cynon Valley Business Park Mountain Ash CF45 4ER	Burney Court Cordwallis Park Maidenhead Berkshire SL6 7BZ	Molly Millars Lane Wokingham RG41 2RZ
Telephone	01443 474647	01628 594500	01189 656300
Fax	01443 474222	01628 789400	01189 656356
Website	www.flexicare.com	www.intaventorthofix.com	www.intersurgical.com

Appendix 1: Supplier and product details 38

New suppliers not included the Market Survey tables are indicated by # , as their products became available in the UK after technical testing was completed.

Supplier	Marshall Products Limited	Medis (UK) Limited	Meditech Systems Limited
Address	1 The Maltings Brassmill Lane Bath BA2 3JL	Gee Road Whitwick Business Park Coalville Leicstershire LE67 4NB	Unit 3 Richmar Butt's End Industrial Estate Sturminster Newton Dorset DT10 1AZ
Telephone	08456 128888	01530 830930	01258 471770
Fax	08456 128889	01530 830940	01258 471772
Website	www.marshallproducts.co.uk	www.clinipol.co.uk	www.electrosurgery.co.uk

Supplier	P3 Medical Limited #	ProAct Medical Limited	Smiths Medical Ltd.
Address	1 Newbridge Close Bristol BS4 4AX	9 - 13 Oakley Hay Lodge Great Folds Road Oakley Hay Business Park Northants NN18 9AS	Colonial Way Watford Hertfordshire WD24 4LG
Telephone	01179 728888	0870 9097400	01923 246434
Fax	01179 724863	0870 9097500	01923 255790
Website	www.p3-medical.co.uk	www.proactmedical.co.uk	www.smiths-medical.com

Appendix 1: Supplier and product details 39

New suppliers not included the Market Survey tables are indicated by # , as their products became available in the UK after technical testing was completed.

Supplier	Teleflex Medical U.K.	Vital Signs Limited
Address	Stirling Road Cressex Business Park High Wycombe Buckinghamshire HP12 3ST	13 - 14 Eldon Way Lineside Industrial Estate Littlehampton West Sussex BN17 7HE
Telephone	01494 532761	08456 444955
Fax	01494 524650	08456 444966
Website	www.teleflexmedical.com	www.vital-signs.co.uk

Appendix 2: Evaluation protocol

Technical evaluation

The technical assessment was performed in the Cardiff University Department of Anaesthetics and Intensive Care medicine. This assessment was based partly on the draft standard for supraglottic airways [78]. Tests on each laryngeal mask comprised:

- measuring the resistance to gas flow (pressure drop across the device at a particular flow)
- whether the 15 mm male connector was correctly sized.

In addition, two further tests were carried out:

- measurement of flexibility
- whether the multiple-use devices could withstand the number of simulated uses as recommended by the manufacturer (including resterilisation).

Resistance to gas flow

A high resistance to gas flow increases the work of breathing for the patient and may also affect the triggering of some ventilators. A maximum limit for pressure drop is not specified in the draft standard [78]. Instead, according to the draft standard, the value obtained from the test must not exceed the value stated by the manufacturer in the Instructions for Use. As it is not mandatory for manufacturers to make this information known to users in this report the average (mean) measured pressure drop for each device is stated.

The resistance to gas flow was measured as the difference in pressure between that measured at the 15 mm male connector and ambient pressure at the cuff end of the laryngeal mask as air flows through the tube. The pressure drop across the laryngeal masks was measured at flows of either 30 or 60 L min^{-1} for sizes 2 and 4, respectively, and is quoted in units of Pascals (Pa, where 100 Pa ≈ 1.02 cmH_2O).

A flow of 60 L min^{-1} was used to determine the pressure drop as this is a peak flow that can commonly occur through a laryngeal mask during use on an adult patient. For example, a patient is typically ventilated using a tidal volume of 10 ml kg^{-1}. A typical adult patient weighing 70 kg will therefore be ventilated with a tidal volume of 700 ml. A peak flow of 60 L min^{-1} is generated if the patient inspires this tidal volume with a sinusoidal waveform over 1.1 s.

Pressure drop results listed in the summary tables are those measured in the inspiratory direction through the laryngeal mask under test in an unused condition ("unflexed"). The test was repeated three times and the average (mean) calculated.

When the laryngeal mask is placed *in situ*, the tube is more curved. Gas flow could be impeded if the tube kinks so pressure drop was also measured when the tube was placed in a template mimicking the typical tube shape during patient use. This is described in the draft standard [78]. One sample of each laryngeal mask was placed in an oven at 37°C for one

hour and then placed into a template so that the tube was shaped into an arc with an angle of 130° and with a radius of 30 and 50 mm for sizes 2 and 4, respectively. The angle and radius specified in the draft standard are from the work of Brain [14]. The increase in pressure drop as a percentage is quoted in the tables. A large increase in pressure drop indicates significant kinking of the tube.

Note: some manufacturers supplied size 2.5 rather than size 2 laryngeal masks for evaluation. These are indicated clearly in the Tables. The pressure drop of size 2.5 devices was measured using the same protocol as that for size 2 devices. The pressure drop across size 2.5 devices is expected to be less than that across size 2 devices as the diameter of the tube will be greater. The manufacturers or suppliers should be contacted to obtain pressure drop data on the size of laryngeal mask required for specific applications.

Connectivity

The 15 mm male connector needs to connect securely with other breathing system components. The 'push-fit' connectors used to connect components on the breathing system are known to be a source of inadvertent disconnection and subsequent inadequate ventilation [67-69].

Dimension tolerances of the 15 mm male conical connector on each LM were checked for compliance with BS EN ISO 5356-1:2004. This specifies that the end of the connector must lie within a certain tolerance in a ring gauge when an axial force of 35 ± 3.5 N is applied whilst rotating the gauge around the connector by 20°.

Flexibility

Rigid LMs may be easier to insert however the tube of more flexible LMs may be easier to move in situ without disturbing the position of the cuff. The flexibility of each device was assessed by measuring the force required to maintain the laryngeal mask with a bend of 90°.

The force required to maintain the laryngeal mask with a bend of 90° was rated as follows:

0 to 1 N	very flexible
>1 to 2 N	flexible
>2 to 3 N	rigid
>3 N	very rigid

Simulated multiple-use

Reliability of re-usable devices after repeated resterilisation is important. Re-usable devices were used in a patient simulator (manikin) and then reprocessed the number of times recommended by the manufacturer. For the Marshall Products 550 LAD, this was 50 times. For all other re-usable laryngeal masks this was 40 times.

Appendix 2: Evaluation protocol

Simulated use consisted of the following

- lubricating the laryngeal mask
- inserting it into a manikin (Laerdal SimMan)
- inflating the cuff
- deflating the cuff
- removing the laryngeal mask
- reinserting the laryngeal mask into the manikin
- inflating and deflating the cuff
- removing the laryngeal mask.

The laryngeal mask was then cleaned by using a toothbrush and a dilute solution of hospital grade detergent and then it was autoclaved at a temperature of 134°C for three minutes.

Appendix 3: Clinical evaluation studies

From the systematic literature search and our review of the published peer-reviewed papers identified it is clear that there is a lack of objective evidence demonstrating the clinical efficacy for most of the laryngeal masks included in this buyers' guide. Randomised controlled trials comparing a new product with clinically established techniques or products provide the highest level of evidence (Table 6). However, other types of studies can be undertaken, e.g. cohort studies or case series, and provide valuable evidence for the clinical efficacy of a new product.

Many clinical studies of laryngeal masks recruit sufficient numbers of patients to demonstrate a difference in one particular outcome measure, such as leak pressure, but are often too small (underpowered) to demonstrate differences in other important outcomes such as first time insertion success rate. Some other outcomes are so rare that studies involving thousands of patients would be required to demonstrate a difference between two devices and thus it is generally difficult to conclude that a particular device is safe.

Although it is common practice for Trusts to carry out audits, as part of the procurement selection process, the value of these studies are inferior to a published RCT, especially as the results are rarely shared to provide evidence for other Trusts. Moreover, procurement audits can expose patients to additional risk, compared with using established products. Scrutiny of the study protocol by the Local Research Ethics Committee (LREC) and requiring formal patient consent are essential for RCTs, improve the research value of the evaluation study and enable dissemination through publication in a peer-reviewed journal.

Table 6 – Levels of evidence [12]

Level	Description
1a	Systematic review with homogeneity of Randomised Controlled Trials (RCT)
1b	Individual RCT with narrow confidence interval
1c	All or none (all patients died before the Rx became available, but some now survive; or when some patients died before the Rx became available, but none now die on it)
2a	Systematic review with homogeneity of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	Systematic review with homogeneity of case control studies
3b	Individual case-control study
4	Case series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Key factors for clinical evaluation studies

[12] Obtained from the Oxford Centre for Evidence-based Medicine, http://www.cebm.net/index.aspx?o=1047

Appendix 3: Clinical evaluation studies

The appropriate type of RCT is an equivalence or non-inferiority study where the aim is to demonstrate that a new laryngeal mask is equivalent to (within certain limits) or no worse than (above a certain limit) an appropriate existing 'gold standard' device, respectively. The study should be powered to demonstrate equivalence or non-inferiority on one primary outcome measure; that is, the number of patients required to be recruited for the study to demonstrate a particular outcome. Primary outcome measures which can be used to assess laryngeal masks are:

- first time success insertion rate
- overall success insertion rate
- time to successful insertion
- quality of airway achieved
- complications of airway management.

Other key outcomes are

- ease of insertion
- sealing pressure
- airway manoeuvres required to maintain a patent airway
- any unplanned removals or replacements of the laryngeal mask during use
- ease of removal
- degree of blood staining on the device
- patient sequelae, for example sore throat.

The outcome of the study is presented in terms of the 95% confidence interval (95% CI) for the difference in the primary outcome measure between the two devices. The 95% CI should lie between the limits or above the lower limit for equivalence and non-inferiority studies, respectively.

The study should be adequately powered to demonstrate equivalence or non-inferiority within fairly narrow limits otherwise there is a danger of claiming equivalence when there is a significant clinical difference between the two devices.

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
LMA-Unique v Classic LMA					
Verghese *et al*, 1998 [15]	RCT of 100 (52% male) mechanically ventilated ASA I-III adults. Patients allocated to two groups: group 1 managed by two consultants; group 2 managed by two trainees. Patients allocated to Classic LMA or LMA-Unique within each group. Sizes used: 4 and 5	1. No overall failures on inserting either device 2. A larger size of LMA-Unique and Classic LMA were required in one and two patients, respectively 3. First time insertion success rate was similar with both devices (86% with Classic LMA vs. 84% with LMA-Unique, p not reported) 4. Blood seen on nine samples of each device 5. Immediate sore throat was reported in five and six patients with the Classic LMA and LMA-Unique, respectively	The LMA-Unique was similar in performance to the Classic LMA	Not clear whether primary outcome was comparison of consultants and trainees or comparison of LMs	One patient requiring a tracheal tube as a replacement for the LMA-Unique was excluded from the analysis
Brimacombe *et al*, 1998 [21]	RCT of 60 (48% female) mechanically ventilated, paralysed adults (ASA I-II), undergoing minor peripheral surgery with nitrous oxide anaesthesia. Sizes used: size 4, F and size 5, M	1. No significant difference in first attempt insertion success rate (98% with Classic LMA vs. 97% LMA-Unique) 2. Insertion times were similar for both devices (12.9 s with Classic LMA vs. 14.7 s with LMA-Unique; p not reported) 3. Airway seal pressure (at 60 cmH_2O intra-cuff pressure) was similar for both (mean: 18.8 cmH_2O with Classic LMA vs. 18.0 cmH_2O with LMA-Unique; p not reported). Airway pressure was also tested at 180 cmH_2O intra-cuff pressure, and was significantly lower with both LMs (mean: 16.5 and 15.6 cmH_2O) 4. Intra-cuff pressure remained stable during N_2O anaesthesia with LMA-Unique but increased significantly every 5 minutes with Classic LMA ($p<0.0001$) 5. No difference in fibreoptic score between LMs; p not reported 6. No difference in blood seen on removal of the two LMs; p not reported	The Classic LMA and LMA-Unique perform similarly with regard to insertion success rates, airway seal and fibreoptic positioning. However, intra-cuff pressure during nitrous oxide anaesthesia is more stable with LMA-Unique. Over-inflation of the cuff produces an inferior seal in both LMs	Findings may not be transferable to non-paralysed patients	Study was powered to detect a 20% difference in airway seal pressure

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
Portex SoftSeal	**vs. Classic LMA**				
van Zundert *et al,* 2003 [16]	RCT of 200 (72% female) spontaneously ventilating adults (ASA I-II) undergoing elective surgery with nitrous oxide anaesthesia. Size used: 4	1. During N_2O anaesthesia, intra-cuff pressure increased significantly more with Classic LMA (55 cmH_2O) than with SoftSeal (2 cmH_2O); p<0.001 2. No significant difference in first attempt insertion success rates between devices (97% with Classic LMA vs. 95% with SoftSeal; p not reported) 3. No significant difference in blood staining on removal of LMA (4% with Classic LMA vs. 0% with SoftSeal; p>0.05) 4. Sore throat at 2 hours postoperatively occurred more frequently with Classic LMA than SoftSeal (20% vs. 10%; p<0.05). There was no difference at 24 hour assessment	During nitrous oxide anaesthesia intra-cuff pressure increases are much greater with Classic LMA compared to SoftSeal, which suggests a need for close monitoring if the Classic LMA is used		Study was powered to detect 35% difference in primary outcome of final intra-cuff pressure. Cuff was inserted partially inflated (manufacturer's guidance is to insert deflated)
Cao *et al*, 2004 [29]	RCT of 138 (42% female) spontaneously ventilating adults (ASA I-IV) undergoing elective surgery with nitrous oxide anaesthesia. Sizes used: 3, 4, or 5 (typically 3 for females and 4 for males)	1. No significant difference in first attempt insertion success rate (84% with Classic LMA vs. 79% with SoftSeal; p>0.05) 2. Fifteen minutes following insertion, intra-cuff pressure (initially set to 60 cmH_2O) had increased significantly more with the Classic LMA compared to SoftSeal (mean: 78 cmH_2O vs. 63 cmH_2O; p<0.001) 3. All patients with successful insertion had normal capnographic tracing, indicating no differences in maintenance of a functional airway between LMs, even though positioning may not have been optimal (marker on airway shaft not being in midline of the incisors: 7% with SoftSeal vs. 5% with Classic LMA) 4. No difference in rates of postoperative sore throat between devices (10% with Classic LMA vs. 14% with SoftSeal; p>0.05)	Both LMs provide an adequate airway for spontaneous ventilation. There was little difference between the first attempt insertion success rate of the Classic LMA compared to the disposable SoftSeal. During N_2O anaesthesia, intra-cuff pressures in both devices increased to greater than the manufacturer's recommended maximum (60 cmH_2O); however, they were significantly lower with SoftSeal	RCT was conducted in two sites, each with a separate anaesthetist performing LM insertion. Unclear whether allocation was concealed	Study was powered to detect 20% differences in primary outcome of first attempt insertion success. Use of anaesthetic drugs was not standardised and left to the discretion of the attending anaesthetist. Patients of all ASA classes were included, and those undergoing surgery in the non-supine position

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
Paech *et al.* (2004) [27]	RCT of 200 spontaneously ventilating females undergoing elective surgery with nitrous oxide anaesthesia. Size used: 4	1. Non-inferiority of SoftSeal to Classic LMA in first attempt insertion success rates (89% with SoftSeal vs. 91% with Classic LMA; p=0.008) 2. SoftSeal took longer to insert than Classic LMA (mean: 45s vs. 35s; p=0.005) 3. SoftSeal was rated by observers as difficult or very difficult to insert more often than Classic LMA (46% vs. 9%; p<0.001) 4. Initial and final intra-cuff pressures (after inflation with 11-12 ml of air) were significantly lower with SoftSeal compared to Classic LMA (median initial: 35 cmH_2O vs. 40 cmH_2O; and final: 28 cmH_2O vs. 48 cmH_2O; p not reported) and decreased during anaesthesia with SoftSeal compared to Classic LMA (median change: -2 cmH_2O vs. +10 cmH_2O; p<0.001) 5. No significant differences in graded fibreoptic view between the devices (p>0.05 for all comparisons) 6. Blood staining on removal of LM occurred more frequently with SoftSeal than Classic LMA (35% vs. 13%; p<0.001) 7. Moderate or severe sore throat at 24 hours postoperatively occurred more frequently with SoftSeal compared to Classic LMA (39% vs. 20%; p=0.014). There was no difference between LMs at 2 hours postoperatively	Both Classic LMA and SoftSeal are suitable for spontaneously breathing patients. Despite the SoftSeal being rated as more difficult to insert, there was no difference in insertion success rates; however there were higher rates of mucosal trauma. During N_2O anaesthesia, cuff pressure did not increase using SoftSeal as it did with Classic LMA	RCT was conducted in two sites, with a total of 52 anaesthetists performing LM insertion. None of the anaesthetists had prior experience with SoftSeal. Findings may not be transferable to male patients	Non-inferiority test used for the primary outcome of insertion success: the hypothesis of inferiority of SoftSeal was rejected as difference was <10%. All patients had a size 4 mask inserted; some users would advocate a size 3 mask in this group (weight: 50-70kg). Funding was provided by Portex Ltd.
Shafik *et al*, 2006 [30]	RCT of 60 (50% female) spontaneously ventilating adults (ASA I-II) undergoing elective surgery. Size: 3, <50kg; size 4, 50-70kg; size 5, >70kg	1. No significant difference in first attempt insertion success rate (96% with Classic LMA vs. 92% with SoftSeal; p not reported) 2. No difference in graded ease of insertion or ease of removal score between devices (p>0.05) 3. Less air was required to inflate the cuff of SoftSeal to obtain an airway seal than with Classic LMA (median: 10ml vs. 15ml; p<0.0001) and intra-cuff pressure produced was also less with SoftSeal (30 cmH_2O vs. 70 cmH_2O; p<0.0001)	Classic LMA and SoftSeal are comparable in terms of insertion success rates and ease of insertion and removal. SoftSeal required less air to inflate the cuff and produce an airway seal, and intra-cuff pressure was subsequently lower		Study was powered to detect 25% difference in the primary outcome of insertion success. LM cuffs were inflated until an airway seal was obtained, not than inflation to a fixed volume or pressure

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
Hanning *et al*, 2006 [31]	RCT of 35 (80% female) paralysed adults (ASA I-II) undergoing elective surgery with nitrous oxide anaesthesia. Size used: not reported. No outcomes tested related to insertion success or LM positioning	1. Airway seal pressure (at 60 cmH_2O intra-cuff pressure) was higher with SoftSeal than with Classic LMA (mean: 21 cmH_2O vs. 16 cmH_2O; p=0.002)	Airway seal pressure is higher with SoftSeal compared to Classic LMA, speculated to be due to differences in cuff materials	Small crossover RCT. LM insertion was performed by two anaesthetists (within subjects, same user performed both insertions), both with limited experience of the SoftSeal	Airway seal pressure was performed by an observer blinded to the LM used
Portex SoftSeal vs. LMA-Unique					
Brimacombe *et al,* 2004 [23]	RCT of 90 (44% female) spontaneously ventilating, paralysed adults (ASA I-II), undergoing elective superficial surgery. Sizes used: size 4, F and size 5, M	1. Significantly greater first attempt insertion success rate with LMA-Unique than SoftSeal (89% vs. 80%; p=0.005) 2. SoftSeal took longer to insert than LMA-Unique (mean: 29s vs. 24s; p=0.0001) 3. No difference in airway seal pressure between devices at any cuff volume (increased from 0-40 ml in 10 ml increments), or at 60 cmH_2O intra-cuff pressure (mean: 24 cmH_2O with LMA-Unique vs. 25 cmH_2O with SoftSeal; p>0.05 for all comparisons) 4. Fibreoptic position was superior with LMA-Unique, achieving grade 4 (vocal cords seen) more often at all cuff volumes (p<0.0004 for all) and at 60 cmH_2O intra-cuff pressure (39% with LMA-Unique vs. 17% with SoftSeal; p=0.0003) 5. No differences in ventilation parameters between devices, e.g. SpO_2, end tidal CO_2, leak fraction, peak airway pressure (p>0.05 for all comparisons) 6. Blood staining on removal of LMA occurred more frequently with SoftSeal at first insertion (31% vs. 9%; p=0.009)	SoftSeal is harder to insert than LMA-Unique and is associated with greater malpositioning and mucosal trauma, possibly related to differences in cuff materials and compliance. However, ventilation was not inferior with SoftSeal. Greater first time insertion success rate suggests that LMA-Unique would be preferable to SoftSeal in situations where immediate airway rescue is required	LM insertion was by two experienced users, who inserted half of the devices each. Their greater experience with LMA Classic may have favoured LMA-Unique, which is more similar in design than SoftSeal. Results may not be transferable to non-paralysed patients	Partial sponsoring was provided by the manufacturers of LMA-Unique. Study was powered to detect a 20% difference for all primary variables
Paech *et al,* 2005 [24]	RCT of 162 spontaneously ventilating adults (70% female) undergoing	1. Non-inferiority of SoftSeal to LMA-Unique in first attempt insertion success rates (91% with SoftSeal vs. 96% with LMA-Unique; p<0.001) 2. SoftSeal took longer to insert than LMA-Unique (mean: 41.5	Equivalence of both devices for successful insertion. SoftSeal is generally harder to insert but requires a lower	RCT was conducted in two sites, each with a separate	Non-inferiority test used for the primary outcome of insertion success: the

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
	minor elective surgery with nitrous oxide anaesthesia. Sizes used: size 3, F ≤70kg; size 4, other F and M	s vs. 38.1 s; p<0.001). This was only when SoftSeal was inserted first in order 3. More anaesthetists rated SoftSeal as being difficult to insert compared to LMA-Unique (OR 6.9, 95% CI 2.4 to 19.9; p<0.001) 4. Intra-cuff pressure was lower with SoftSeal than LMA-Unique (mean: 44 cmH_2O vs. 50 cmH_2O; p<0.001); significant difference in change of cuff pressure during N_2O anaesthesia (-3cm H_2O with SoftSeal vs. +16 cmH_2O with LMA-Unique; p<0.01) 5. Inability to view vocal cords was more common with LMA-Unique (27% vs. 17%; p<0.05) 6. Blood staining on removal of LMA occurred more frequently with SoftSeal at first insertion (10% vs. 4%; p<0.001) although not overall	cuff pressure to seal the airway, possibly due to differences in cuff materials and compliance. Either device is suitable for airway management	anaesthetist performing LM insertion. Anaesthetists had little experience with LMA-Unique	hypothesis of inferiority of SoftSeal was rejected as difference was <10%. The RCT used lower intra-cuff pressures than used in other RCTs. Cuff was inserted partially inflated (manufacturer's guidance is to insert deflated)
Cook *et al*, 2005 [25]	RCT of 100 (51% female) spontaneously ventilating adults (ASA I-III) undergoing elective surgery. Sizes used: size 3, F 40-50kg; size 4, other F; size 5, M (*continued on next page)*	1. No significant difference in first attempt insertion success rate (68% with SoftSeal vs. 78% with LMA-Unique; p=0.36), or overall successful insertion (90% with SoftSeal vs. 100% with LMA-Unique; p=0.056) 2. Significantly more attempts were required to successfully insert the SoftSeal than the LMA-Unique (p=0.041). 3. SoftSeal took longer to insert than LMA-Unique (median: 23 s vs. 20 s; p=0.04) 4. More manipulations of the LMA were required with SoftSeal overall (69 vs. 30; p<0.0001), and there were more complications during insertion (31 vs. 9; p=0.048), e.g. coughing, hypoxia, loss of airway 5. No significant differences between the devices in graded fibreoptic view (p=0.26) 6. Airway seal pressure (at 60 cmH_2O intra-cuff pressure) was higher with SoftSeal than LMA-Unique (median: 26.5 cmH_2O vs. 20.5 cmH_2O; p=0.005) 7. No significant difference in ventilation success between devices (passed tests of adequate ventilation: 41 with SoftSeal vs. 48 with LMA-Unique; p=0.051)	SoftSeal performed less well and caused more complications than LMA-Unique, although differences in insertion success were non-significant. However, general performance favoured LMA-Unique with fewer complications and better positioning of the device. Although seal was improved with SoftSeal, there was no difference in ventilation success	Study was terminated after only 100 patients (of the 300 planned) due to marked difference in LM performance. No record was made of who inserted the device	This study was supported by the manufacturers of LMA-Unique

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
		8. Subjective ease of insertion ratings favoured LMA-Unique ($p<0.0001$) 9. Postoperative sore throat occurred more frequently with SoftSeal than LMA-Unique ($p=0.015$) 10. No significant difference in blood staining on removal of LMA (18% with SoftSeal vs. 4% with LMA-Unique; $p=0.06$)			
Portex SoftSeal vs. LMA-Unique (vs. Cobra perilaryngeal airway)					
van Zundert *et al*, 2006 [26]	RCTof 320 adults (ASA I-III; 81% female) undergoing elective surgery. Sizes used: 3, >30-50 kg; 4, >50-70 kg; 5, >70 kg	1. LMA-Unique and the SoftSeal did not provide adequate airways in 4 and 1 patient, respectively 2. Both LMs inserted first time in remaining patients (103 and 102 patients, respectively) 3. Oropharyngeal leak pressure was lower with LMA-Unique than with SoftSeal (25 cmH_2O vs. 31 cmH_2O) 4. Endoscopic score was better with the SoftSeal than with the LMA-Unique 5. Increase in intracuff pressure were similar (9.7 and 9.6 mmHg for the LMA-Unique and SoftSeal, respectively)	Ease of insertion of both LMs was similar	Large majority of female patients in study group. Analysis was on three-group study (including the Cobra perilaryngeal airway)	Cuff was inserted partially inflated (manufacturer's guidance is to insert deflated)
Portex SoftSeal vs. LMA-Unique vs. Classic LMA					
Tan *et al*, 2005 [22]	RCT of 135 spontaneously ventilating adults (ASA I-II) undergoing elective surgery with nitrous oxide anaesthesia. Sizes used: 3, 4, and 5 (typically 3 for females and 4 for males) (*continued on next page)*	1. SoftSeal took longer to insert than Classic LMA (mean: 49.4 s vs. 32.9 s; $p=0.012$) but was not significantly different from the insertion time for LMA-Unique (mean: 39.6 s; $p>0.05$) 2. No significant differences in first attempt insertion success rates between devices (80% with Classic LMA vs 77% with LMA-Unique vs. 62% with SoftSeal; $p>0.05$ for comparisons) 3. Airway seal pressure (at 60 cmH_2O intra-cuff pressure) was higher with SoftSeal (mean: 21 cmH_2O) than Classic LMA (mean: 17 cmH_2O; $p=0.015$) or LMA-Unique (mean: 16 cmH_2O; $p=0.001$) 4. Blood staining on removal of LM occurred more frequently	Insertion times are less with Classic LMA than either of the disposable masks, but only significant compared to SoftSeal. First time insertion success rates are less than expected (staff were novice) with all of the LMs; greater success may be seen with more experienced staff. Airway seal pressure is improved with SoftSeal compared to either of the	Nine trainees performed nine insertions each. In cases of failed insertion, the LM was inserted by an experienced user and insertion times were excluded from the analysis; as this occurred mostly with the disposable LMs, insertion	Insertion times for patients with failed insertion were excluded from analysis. Data may be skewed in favour of disposable LMs. All insertions were by trainees with no prior anaesthetic experience. Airway seal pressures and presence of blood on

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
		with SoftSeal (32%) than Classic LMA (14%; p=0.046) or LMA-Unique (9%; p=0.012) 5. Postoperative sore throat occurred more frequently with both SoftSeal (42%) and Classic LMA (41%) compared to LMA-Unique (14%) (p=0.006)	other devices, but the SoftSeal is also associated with higher rates of mucosal trauma. Higher rates of sore throat in general, for all devices, likely to be the result of inexperienced users	times may be biased in favour of them	LM and postoperative sore throat were recorded by an observer blinded to the type of LM used. Study was powered to detect 15s difference in the primary outcome of insertion time
Portex SoftSeal vs. LMA-Unique vs. Ambu LM					
Francksen *et al*, 2007 [32]	RCT of 120 females (ASA I-III) undergoing minor obstetric surgery with positive pressure ventilation. Size used: 4	1. No significant difference in first attempt insertion success rate (87% with all devices) 2. Insertion time was shorter with Ambu LM (median: 14s) than with the other devices (LMA-Unique: 19 s; p<0.005; SoftSeal: 20 s; p<0.0001) 3. Ease of insertion was as graded excellent in 75% of patients using LMA-Unique, 70% with Ambu, and 65% with SoftSeal; significance not reported 4. Intra-cuff pressures (inflated to 20, 30 and 40 ml volumes) were lowest with SoftSeal 5. Airway seal pressures were significantly higher with both SoftSeal and Ambu LM compared to LMA-Unique (at all cuff volumes) 6. No differences in ventilation parameters between devices, e.g. SpO_2, expiratory tidal volume, peak airway pressure (p>0.05 for all comparisons) 7. No differences in complication rates or postoperative morbidity, i.e. blood on LM at removal or patient reported sore throat (reported as 'no difference', p not provided)	Ambu LM, SoftSeal, and LMA-Unique are all comparable for insertion success, and do not differ in rate of complications or postoperative morbidity. SoftSeal provides the highest airway seal with the lowest intra-cuff pressures, but this was not associated with improved ventilation, and problems with insertion and ease of use were more frequent. With all devices, intra-cuff pressures were generally above recommended values. Increasing cuff volume was also not associated with clinically beneficial improvement in airway seal	Findings may not be transferable to male patients	Cuff was inserted partially inflated (manufacturer's guidance is to insert deflated). Study was powered to detect 20% difference in the primary outcome of insertion time

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
Ambu LM vs. Classic LMA					
Sudhir *et al*, 2007 [34]	RCT of 50 spontaneously ventilating adults (ASA I-II) undergoing elective surgery. Sizes used: size 3, <50kg; size 4, 50-70kg; size 5 >70kg	1. Non-inferiority of Ambu AuraOnce to Classic LMA in first attempt insertion success rates (92% with Ambu AuraOnce vs. 84% with Classic LMA; p=0.22) 2. Using a visual analogue scale (0 mm being impossible, 100 mm being easy), Ambu LM was rated easier to insert than Classic LMA (median: 86.5 mm vs. 84 mm; p=0.017) although the difference was small 3. Intra-cuff pressures required to obtain an airway seal were lower with Ambu LM compared to Classic LMA (median: 18 cmH_2O vs. 27 cmH_2O; p=0.007), while there was no difference in cuff volume (10 ml) 4. No difference in the rates of complications between LMs, e.g. cough, laryngospasm, or loss of airway (p not reported)	Insertion success rates are similar for both the Classic LMA and Ambu AuraOnce. Ease of insertion was better with Ambu LM, and the median cuff pressures when a good airway seal were obtained were lower than with Classic LMA. Ambu AuraOnce is therefore an effective alternative to the Classic LMA	Anaesthetist performing insertions had much greater experience with Classic LMA than Ambu AuraOnce. Unclear whether allocation concealed	Non-inferiority test used for the primary outcome of insertion success: the hypothesis of inferiority of Ambu AuraOnce was rejected as difference was <15%. Airway seal pressure was assessed by absence of audible leak (most RCTs assess by closure of the expiratory valve at flow 3L/min and noting airway pressure at equilibrium)
Ng *et al*, 2007 [33]	RCT of 105 spontaneously ventilating females (ASA I-II) undergoing minor gynaecological surgery with nitrous oxide anaesthesia. Sizes used: size 3, 30-50kg; size 4, 50-70kg; size 5, >70kg	1. No significant difference in insertion time between Classic LMA and Ambu AuraOnce (26 s vs. 21 s; p=0.26) 2. No significant difference in first attempt insertion success rates between devices (83% with Classic LMA vs. 92% with Ambu AuraOnce; p=0.24) 3. No significant difference in airway seal pressure (at 60 cmH_2O intra-cuff pressure) between Classic LMA and Ambu AuraOnce (mean: 21 mmHg [28.6 cmH_2O] vs. 20 mmHg [27.2 cmH_2O]; p=0.43) 4. Observers rated Ambu AuraOnce as being easier to insert than Classic LMA (p=0.016) 5. No significant difference in haemodynamic stability (blood pressure or heart rate) upon insertion of either LM (p>0.05 for both)	Classic LMA and Ambu AuraOnce are comparable for insertion success, insertion time and airway seal pressure. The Ambu AuraOnce was graded as being easier to insert, due to folding of the LMA tip on insertion of Classic. The slightly higher incidence of pharyngeal trauma and sore throat require larger studies to confirm the findings	LM insertion was performed by four different anaesthetists. Study was conducted in Asian women only; findings may not be transferable to other females or male patients	Study powered to detect 30% difference in primary outcome of time to insertion. One unsuccessful Ambu insertion was changed to Classic LMA and analysed as Ambu AuraOnce

Appendix 4: Clinical evidence in RCTs

Table 7 – Published Randomised Controlled Trials (RCT) comparing LMs of the same type

Reference	Methods	Results	Author's summary conclusions	Limitations	Notes
	(*continued on next page)*	6. Blood staining on removal of LM occurred more frequently with Classic LMA than Ambu AuraOnce (4/55 vs. 2/50; p not reported) 7. Postoperative sore throat was noted more often with Classic LMA (2/55 vs. 0/50; p not reported) 8. No cases of other complications were recorded (e.g. regurgitation, lip or tongue injury)			
Shariffuddin *et al,* 2008 [35]	RCT of 40 (65% female) spontaneously ventilating, paralysed adults (ASA I-II) undergoing elective surgery. Sizes used: size 3, 30-50kg; size 4, 50-70kg; size 5, >70kg	1. Airway seal pressure (at 60 cmH_2O intra-cuff pressure) was higher with Ambu AuraOnce than with Classic LMA (mean: 19.2 cmH_2O vs. 15.3 cmH_2O; p = 0.004) 2. First attempt insertion success rates were greater with Ambu AuraOnce than with Classic LMA (98% vs. 88%; p = 0.02) 3. Insertion times were similar for both devices (23.9 s with Classic LMA vs. 26.0 s with Ambu AuraOnce; p=0.76) 4. More patients required manipulations to the LM to establish a patent airway with the Ambu AuraOnce than the Classic LMA (15% vs. 2.5%; p=0.045) 5. No significant differences in graded fibreoptic view between the devices (p=0.8) 6. Optimal ventilation was maintained with both devices 7. No significant difference in rates of mucosal injury between devices	Ambu AuraOnce is as effective as the Classic LMA in establishing an effective airway. Although insertion times were similar, Ambu AuraOnce was easier to insert and also had a greater airway seal pressure	Small study. Findings may not be transferable to non-paralysed patients	Study powered to detect 30% difference in primary outcome of airway seal pressure. One failed ventilation following Ambu insertion was changed to Classic LMA and analysed as Ambu AuraOnce
Single-use Intavent Orthofix Flexible LMA vs. reusable Intavent Orthofix Flexible LMA					
Flynn *et al,* 2007 [36]	RCT of 100 (50% female) spontaneously breathing children aged 2-12 years (ASA I-II) undergoing day case dental extraction under general anaesthesia using nitrous oxide. Sizes used: size 2, 10-20 kg; size 2½, 20-30 kg; size 3, >30 kg	1. Equivalence of reusable and single-use flexible LMAs in terms of first attempt insertion success rates (94% vs. 90%; p=0.36) 2. No significant difference in subjective ease of insertion (94% reusable graded as 'easy' vs. 92% single use; p=0.5). 3. No significant difference in subjective ease of manual ventilation (100% reusable graded as 'easy' vs. 96% single use; p=0.25) 4. No significant difference in tolerance on recovery from anaesthesia, e.g. rates of coughing or blood on LM	Equivalence of both the reusable and single-use flexible LMs for performance during paediatric dental surgery, with no evidence of airway trauma from either device	Insertion was by three anaesthetists, all experienced with use of flexible (reinforced) LMs	Equivalence test used for the primary outcome of insertion success: the hypothesis of equivalence being accepted if difference was <15%. No information is provided on dental surgery conditions

Buyers' guide: Laryngeal masks

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