

LarySeal™ MRI

Laryngeal Mask Airway

Product Data Sheet

PRODUCT: LarySeal™ MRI



DESCRIPTION / FUNCTION

The LarySeal™ MRI Laryngeal Mask Airway is used for patients who require anaesthesia, artificial respiration and other types of assisted respiration. It is an alternative method of maintaining the patency of the airway against the traditional use of an Endotracheal Tube.

LarySeal™ MRI provides the same benefits of LarySeal™ Clear with the added benefit of a metal-free inflation valve, allowing LarySeal™ MRI to be used safely within the MRI suite.

It is used in emergency departments, general surgery and ICU. It has particular advantages over ET tubes where the trachea is difficult to insert during neck and back operations which require special positions, examination of trachea and larynx and the clearing of foreign substrates in the trachea.








WARNINGS

- Do not use if packaging is open or damaged
- Consult Instructions For Use
- Single use. Do not reuse
- After use, this product is contaminated clinical waste and may be a potential biohazard. Handle and dispose of in accordance with hospital policy and applicable local guidelines and regulations.

SPECIFICATION / KEY FEATURES

- Medical Grade, DEHP free PVC
- Latex free
- Single use
- Thickness of main tube wall reduces the risk of crushing
- The satin surface finish of the LarySeal MRI cuff provides a similar texture to silicone, whilst ensuring ease of insertion
- ISO 5356 compliant 15mm male connector provides a universal connection
- Single use eliminates the need for cleaning and re-sterilising, saving time and cost
- Supplied in a sterile state – Ethylene Oxide (EO) Gas
- The metal free construction of the valve allows the LarySeal MRI to be used in an MRI suite
- Ease of identification of sizing by colour coded pilot balloon

PRODUCT RANGE & PART NUMBERS

Product Code	Description	Quantity
038-94-410	LarySeal MRI Size 1 < 5kg 	10
038-94-415	LarySeal MRI Size 1.5 5kg -10kg 	10
038-94-420	LarySeal MRI Size 2 10kg - 20kg 	10
038-94-425	LarySeal MRI Size 2.5 20kg - 30kg 	10
038-94-430	LarySeal MRI Size 3 30kg - 50kg 	10
038-94-440	LarySeal MRI Size 4 50kg - 70kg 	10
038-94-450	LarySeal MRI Size 5 70kg - 100kg 	10

MATERIALS

Component	Material
Cushion	Polyvinyl Chloride (PVC)
Shell	Polyvinyl Chloride (PVC)
Main Tube	Polyvinyl Chloride (PVC)
Inflation Tube	Polyvinyl Chloride (PVC)
Pilot Balloon	Polyvinyl Chloride (PVC)
15mm Connector	Acrylonitrile Butadiene Styrene (ABS)
Valve	Polycarbonate (PC) / Polyester / Silicone
Valve tag	Polypropylene (PP)

LATEX CONTENT

Flexicare LarySeal™ MRI does not contain natural rubber Latex.

DEHP CONTENT

Flexicare LarySeal™ MRI does not contain phthalate DEHP.

SINGLE USE

Flexicare LarySeal™ MRI is single use.

STERILITY

Flexicare LarySeal™ MRI is supplied sterile by Ethylene Oxide (EO) gas method.

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life of five years from the date of sterilisation. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product packaging.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Primary - Top Web – EO permeable High-density Polyethylene (HDPE) filaments
Thermoform Tray – Polyvinyl Chloride (PVC)
Secondary – Carton / Box Cardboard