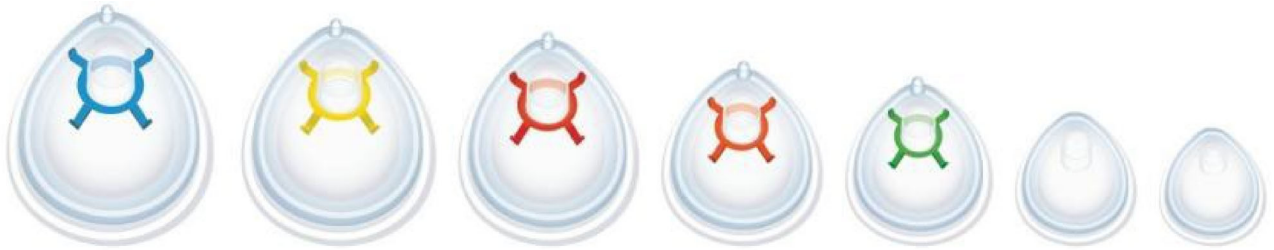


Anaesthesia Face Masks (Inflatable)

Product Data Sheet

PRODUCT: Anaesthesia Face Masks (Inflatable)**DESCRIPTION / FUNCTION**

Flexicare's Anaesthesia Face Masks (Inflatable) are designed to channel anaesthesia gases or mixtures of oxygen to the patient for inhalation via the mouth and nose. Anaesthesia masks are to be used in conjunction with anaesthesia and ventilator breathing systems. They are compatible with all standard catheter mounts and breathing systems with 22mm and 15mm connectors.

WARNINGS / PRECAUTIONS

- Do not use if the packaging is open or damaged.
- Single use device only. Do not re-use, sterilise or autoclave.
- After use, this product is contaminated 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

- Clear face piece allows visual observation of patient status.
- Compatible with all standard catheter mounts and breathing systems with 22mm & 15mm connectors.

PRODUCT RANGE & PART NUMBERS

Product Code	Product Description
038-51-390	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Extra Large Adult Size 6
038-51-390NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Extra Large Adult Size 6, no Hook
038-51-400	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5
038-51-400NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5, no Hook
038-51-400SFN	Anaesthesia Face Mask Single Use Unscented Large Adult Size 5
038-51-400SFNH	Anaesthesia Face Mask Single Use Unscented no Hook Ring Large Adult Size 5
038-51-410	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4
038-51-410NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4, no Hook
038-51-410SFN	Anaesthesia Face Mask Single Use Unscented Adult Size 4
038-51-410SFNH	Anaesthesia Face Mask Single Use Unscented no Hook Ring Adult Size 4
038-52-415	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3
038-52-415NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3, no Hook
038-52-415SFN	Anaesthesia Face Mask Single Use Unscented Large Child Size 3
038-52-415SFNH	Anaesthesia Face Mask Single Use Unscented no Hook Ring Large Child Size 3
038-52-420	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2
038-52-420NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2, no Hook
038-52-420SFN	Anaesthesia Face Mask Single Use Unscented Medium Child Size 2
038-52-420SFNH	Anaesthesia Face Mask Single Use Unscented no Hook Ring Medium Child Size 2
038-52-430	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1
038-52-430NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1, no Hook
038-52-430SFNH	Anaesthesia Face Mask Single Use Unscented Small Child Size 1
038-53-440	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0
038-53-440NH	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0, no Hook
038-53-440SFNH	Anaesthesia Face Mask Single Use Unscented Green Size 0

- Soft inflatable cushion can be inflated or deflated to enhance the seal to suit the patient's anatomical contours.
- Available in seven sizes, from neonatal to extra-large adult.
- All masks have their size moulded into the mask shell. The coloured hooks (where present) also indicate the mask size, sizes 2 to 6 indicated by colours green, orange, red, yellow and blue respectively.

MATERIALS

Component	Material
Cushion	Polyvinyl Chloride
Cushion Mask Shell	Polyvinyl Chloride
Non-return Valve	Acrylonitrile Butadiene Styrene (ABS) / Silicone / Polyvinyl Chloride (PVC) / Polyoxymethylene (POM) / Stainless Steel
Hook	Polypropylene (PP)

LATEX CONTENT

Flexicare's Anaesthesia Face Masks (Inflatable) do not contain natural rubber latex.

DEHP CONTENT

Flexicare's Anaesthesia Face Masks (Inflatable) do not contain phthalate DEHP.

PRODUCT USE

Flexicare's Anaesthesia Face Masks (Inflatable) single use devices.

STERILITY

Flexicare's Anaesthesia Face Masks (Inflatable) are supplied non-sterile.

STORAGE

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

SHELF LIFE

Flexicare declares a shelf life of 5 years from the date of manufacture. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product pouch.

DISPOSAL CONSIDERATIONS

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

PACKAGING MATERIALS

Primary – Polybag – Polyethylene (PE)

Secondary – Carton / Box - Cardboard

Signature: Chris Kooge
Chris Kooge (Aug 25, 2021 13:44 GMT+2)

Email: chris.kooge@flexicare.com

Signature: Geraint Whitcombe
Geraint Whitcombe (Sep 2, 2021 18:21 GMT+1)

Email: geraint.whitcombe@flexicare.com

Signature: Joel Biddle
Joel Biddle (Sep 3, 2021 08:09 GMT+1)

Email: joel.biddle@flexicare.com











PDS-000014 v3 Anaesthesia Face Masks (Inflatable)

Final Audit Report

2021-09-03

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