

## In Instructions For Use

The medical device is not supplied individually. Only one copy of the instructions for use is provided per box and should therefore be kept in an accessible location for all users.

**NOTE:** Distribute instructions to all product locations and users. These instructions contain important information for the safe use of the product. Read these instructions for use in their entirety, including warnings and cautions before using this product.

Failure to properly follow warnings, cautions and instructions could result in serious injury or death to the patient.

**WARNING:** A WARNING statement provides important information about a potentially hazardous situation, which, if not avoided could result in death or serious injury.

**CAUTION:** A CAUTION statement provides important information about a potentially hazardous situation, which if not avoided could result in minor or moderate injury.

**Anaesthetic Facemask:** To deliver anaesthetic gas and oxygen to a patient.

**Indications**

Anesthesia masks should be positioned to create an airtight seal around the patient's mouth and nose and attached to a breathing system. They can be used to induce anesthesia for patients of any age, and may also be used during manual resuscitation and ventilation.

**Contraindications**

Patients with abnormal facial anatomy or facial injury.

**Product Use:** The product is intended for single use with a range of anaesthetic agents, respiratory and anaesthetic equipment which may be used in the acute and non-acute environment under the supervision of appropriately qualified medical personnel.

Anaesthetic face masks are supplied with a variety of styles and sizes to meet a variety of clinical needs and provide user choice. Always use the correct mask for the correct breathing system and respiratory equipment using a push and twist action to guarantee a safe and secure connection to breathing system.

3. Ensure that an appropriately sized mask is selected based upon the patient's size and weight.

4. Once selected ensure that an airtight seal has been achieved allowing delivery of prescribed gas and manual ventilation.

5. Give consideration to any impact that the internal volume of the device may have upon the effectiveness of the prescribed ventilation. The clinician should assess this on an individual patient basis.

**In-Use Check**

1. Monitor the mask throughout use and replace if visual contamination occurs.

**Caution**

1. The mask is only to be used under the supervision of appropriately qualified medical personnel.

2. The mask should be used with equipment with 22mm M/15mm F connector which complies to ISO 5356.

3. The product must be cleaned, packed and ready for use. Do not use the product if the packaging is damaged.

4. The products have been designed, validated and manufactured for single use.

5. The product must not be re-used, cleaned or sterilized.

**FOR USA: Rx ONLY:** Federal law restricts this device to sale by or on the order of a physician.

**Warning**

1. Prior to use, check that all system components are free of obstructions and foreign bodies.

2. Connect/disconnect the tapered connection of the mask to the appropriate breathing system and respiratory equipment using a push and twist action to guarantee a safe and secure connection to breathing system.

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