

# AeroKEE™

## Single-Use Endoscopic Procedure Mask

### Instructions for Use

**REF** HL-AERO-F-1  
**ARTG** 523640  
**Class** Medical Device Class I  
**Doc No.** HL-IFU-AERO-F-2-AU  
**Rev.** 02 | 2026-04-17  
**GMDN** 67755

**Manufacturer**  
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**ARTG Identifier: 523640 | ARTG Start Date: 19/02/2026**

### 1. INTENDED USE

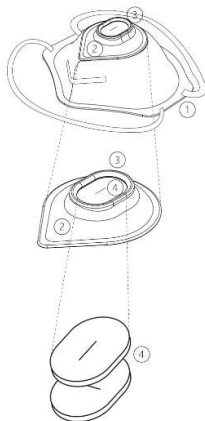
AeroKEE™ Single-Use Endoscopic Procedure Mask is designed for use during oral or transnasal gastroscopy, bronchoscopy, or nasal endoscopy to support workflow hygiene by helping to organize fluid droplets and procedure-generated aerosols around the insertion area.

<b>Intended User</b>	Healthcare professionals trained in endoscopic procedures, or patients under their direction
<b>Patient Population</b>	For use on patients assessed by the responsible healthcare professional as appropriate.
<b>Paediatric Use</b>	Not evaluated. Use should be determined by the responsible healthcare professional.

### 2. CONTRAINDICATIONS AND LIMITATIONS

- Do not use if patient is known or suspected to be allergic to any material in the device.
- Do not use where a face covering may compromise airway management, ventilation, oxygen delivery, anaesthesia equipment, capnography, or clinical monitoring.
- Do not use with positive-pressure ventilation or sealed oxygen/anaesthesia masks unless assessed by the responsible healthcare professional.
- Not respiratory protective equipment; does not replace PPE, respirators, engineering or ventilation controls, or facility infection-control procedures.
- Not a sterile barrier; must not be used where a sterile device or sterile barrier is required.

### 3. PRODUCT DESIGN



- Secure Fit** Flexible straps and adjustable nose clip; adapts to various facial anatomies.
- Clear Panel** Transparent window for continuous visual monitoring of the patient's nose and mouth.
- Insertion Port** ~20 x 30 mm; fits commonly used flexible endoscopes. Smooth interface reduces risk of scope surface abrasion.
- Sponge Interface** Dual-layer medical-grade sponge with central slit; allows smooth insertion/withdrawal; assists with fluid localisation.

### 4. MATERIALS AND LATEX STATEMENT

- Patient-contacting materials include: needle-punched cotton.
- This product is not made with natural rubber latex.

### 6. WARNINGS AND PRECAUTIONS

- Single-use only. Do not reuse, reprocess, or resterilise.
- Supplied non-sterile. Do not sterilise or resterilise.
- Intended for a single patient only. Do not share with others.
- Discontinue use if discomfort, breathing difficulty, or allergic reaction occurs.
- Do not use if packaging is damaged or product is visibly contaminated.
- Do not use on individuals with difficulty breathing; may cause respiratory discomfort if improperly fitted.

### 7. CARE AND STORAGE







- Store in original packaging in a clean, dry place away from direct sunlight, heat, moisture, and contamination.
- Do not fold or compress unnecessarily; may compromise integrity.
- Do not use after expiry date.
- LOT and EXP (YYYY-MM-DD) are printed on the product and the box.

### 8. PACKAGING SPECIFICATIONS

Config.	Qty	Details
<b>Inner box</b>	8 pcs	REF: HL-AERO-F-1
<b>Carton</b>	96 pcs (12x8)	LOT & EXP (YYYY-MM-DD) in box

### 9. SYMBOLS

Symbols per ISO 15223-1:2021 and applicable ISO 7000 references.

Symbol	Description
	Non-sterile
	Caution
	Do not use if packaging is damaged
	Keep dry
	Keep away from sunlight
	Single use only

## 5. DIRECTIONS FOR USE

### Pre-use inspection

- Check package integrity, expiry date, and lot number before use.
- Do not use if packaging is damaged or product is contaminated, torn, wet, or expired.

### Application steps

1. Remove mask from packaging and inspect for damage.
2. Position mask over patient's nose and mouth; ensure clear panel covers both.
3. Secure straps behind patient's head.
4. Adjust nose clip for a snug fit over the bridge of the nose.
5. Confirm patient comfort and that monitoring access (O<sub>2</sub> delivery, capnography, airway) is not compromised.
6. Insert endoscope through insertion port; proceed per facility protocol and endoscope manufacturer's IFU.

### During the procedure

Monitor patient throughout; discontinue use if breathing difficulty, discomfort, or adverse reaction occurs.

### Removal and disposal

Grasp straps and carefully pull away from patient's head. Dispose of as clinical waste per facility procedures and applicable Australian state/territory requirements.



Consult instructions for use



Catalogue number / REF



Batch code / LOT



Use-by date / EXP



Manufacturer



Medical device

## 10. COMPLAINTS AND ADVERSE EVENTS

For complaints or adverse events in Australia, contact HEALKEE MEDICAL PTY LTD at sales@healkee.com. Adverse events will be reported to the TGA as required.

## 11. IMPORTANT NOTE

These instructions must be read and followed carefully before use. Failure may affect device performance and patient safety. This document does not replace clinical training, professional judgement, the endoscope manufacturer's instructions, or facility protocols.

Subject to document control. Current effective version maintained by HEALKEE MEDICAL PTY LTD.

**HEALKEE MEDICAL PTY LTD**

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