HealKEE MEDICAL

ISO 13485 CERTIFIED

AeroKEE™ Single-Use Procedure Barrier Mask

- Designed & Developed in Singapore -

Exposure-Reduction Barrier for Endoscopic Procedures
Reduce Exposure to Fluid Droplets and Procedure-Generated Aerosols in Oral and Transnasal Gastroscopy, Bronchoscopy, Nasal Endoscopy

YOU Deserve The Best Care

Patent Pending in Multiple Jurisdictions, Singapore Application No. 10202503408P
(Images shown are for illustration purposes only, actual product may vary)

Clinical Evidence of Aerosol and Droplet Exposure During Endoscopic Procedures

The following publications report on aerosol generation and exposure during endoscopic procedures. They do not imply disease prevention or product efficacy

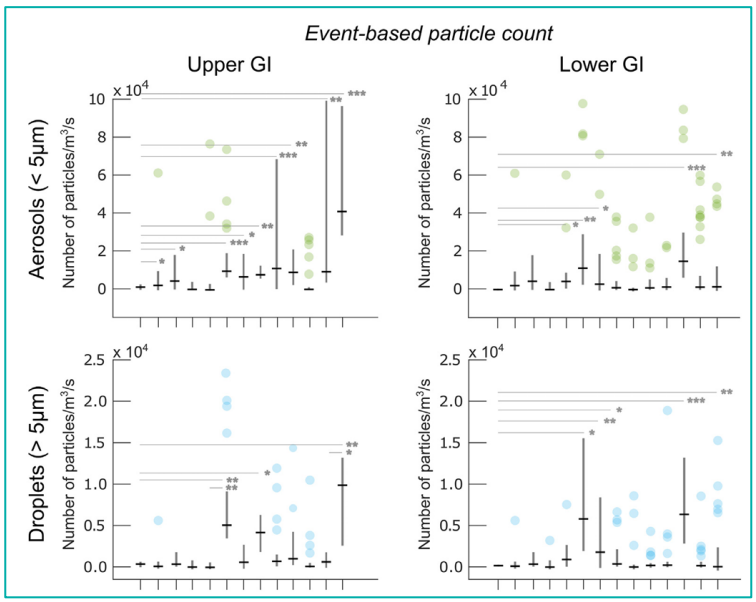
The following medical procedures have been reported to generate aerosols and droplets during clinical practice:

1

- ***bronchoscopy***
- ***upper gastro-intestinal endoscopy***
- ***upper ENT airway procedures involve respiratory suctioning*** *(1)*

Public Health England

2



"GI endoscopy performed through the mouth, nose, or rectum generates measurable quantities of droplets and aerosols" *(2)*

3

"Aerosol-generating procedures may increase exposure for endoscopy personnel, including nurses, technicians, and anesthesia staff... *While upper gastrointestinal endoscopy is an aerosol-generating procedure"* *(3)*

4

"Clinical studies indicate that aerosol-generating procedures can increase exposure to airborne particles for personnel working in endoscopy units" *(4)*

1. *COVID-19: Guidance for maintaining services within health and care settings*
2. *Frank Phillips et al. Aerosol and droplet generation in upper and lower GI endoscopy: whole procedure and event-based analysis. Volume 96, No. 4 : **2022** GASTROINTESTINAL ENDOSCOPY 603*
3. *Bilal M， Simons M， Rahman AU， et al. What constitutes urgent endoscopy? A social media snapshot of gastroenterologists views during the COVID-19 pandemic[J]. Endosc Int Open， 2020，8 (5) :E693-698. DOI: 10.1055/a-1153-9014 .*
4. *ASGE Quality Assurance in Endoscopy Committee. Gastrointestinal Endoscopy, 2018.*

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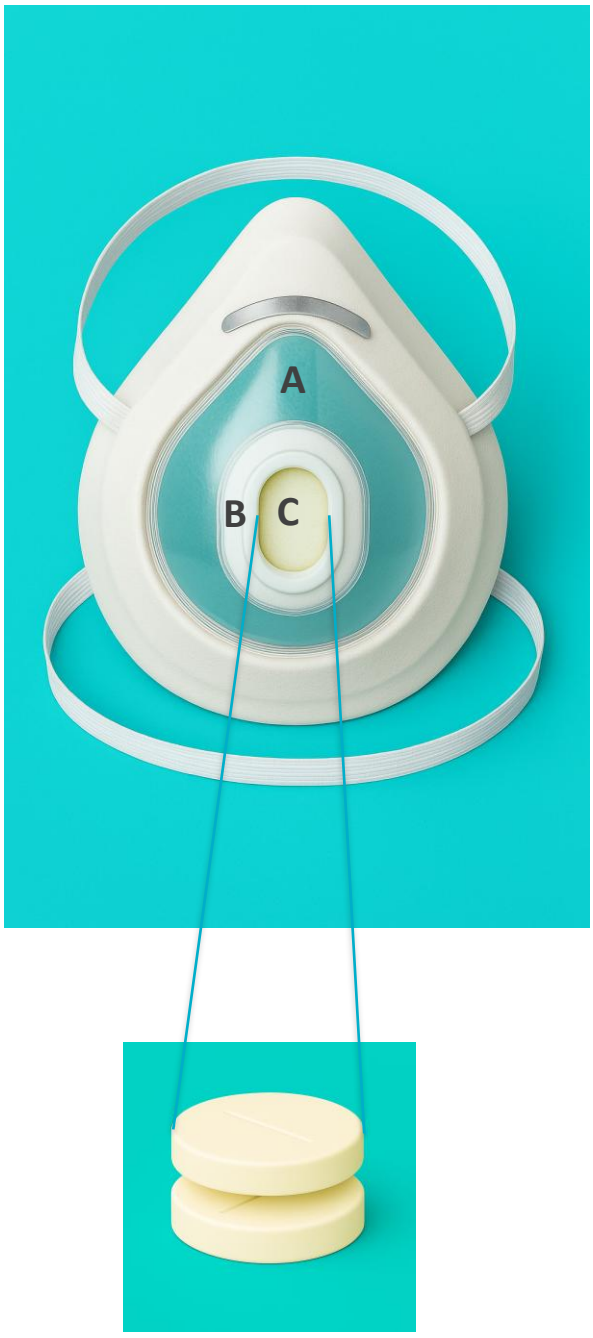
Small Procedure Barrier, Smart Exposure Management

Barrier Features for Endoscopic Procedures

- Soft, skin-contact cushion reduces pressure and avoids interference with nasal oxygen cannula
- Flexible straps and adjustable nose clip adapt to various face shapes
- Quick to put on and remove during workflow



A. Anti-fog transparent window

- Maintains clear visibility of the mouth and nose during endoscope manipulation

B. Smooth insertion port

- Minimizes scratching of scopes while maintaining handling comfort
- Wide endoscope channel (Ø 20–30 mm) suitable for common GI and ENT instruments
- Designed to support both oral and transnasal insertion angles

C. A dual-layer medical-grade sponge with a vertical central slit

- Supports easy insertion and withdrawal of the scope
- Helps reduce dispersion of droplets around the insertion point
- Collects superficial moisture from the scope to reduce immediate soiling

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Product Information

Validation

Test Property & Methodology		Rating
ASTM F2100		Pass
Biocompatibility	Cytotoxicity Test-ISO10993-5	Pass
	Irritation & Sensitization-ISO 10993-10:2021	Skin-contacting materials are listed in FDA and EU CE exemption lists

Specification

Intended Use	Designed for use during oral or transnasal gastroscopy, bronchoscopy, or nasal endoscopy (single-use) as a procedural barrier to help reduce direct exposure to fluid droplets and procedure-generated aerosols
Material Information	Mask Body Components • Needle-punched cotton • Melt-blown fabric Metal nose clip (aluminum alloy) • Transparent window/scope insertion port/sponge • Polypropylene (PP) material
Color	White main body of masks, white scope insertion port and polymer sponge, transparent plastic film
Storage	In a clean, dry place when not in use. Avoid storing in direct sunlight or extreme temperatures

Order Information

Item # & **Description**	*HL-AERO-F-1, AeroKEE™ Single-Use Procedure Barrier Mask*			
Unit	**Quantity**	**Dimensions(L*W*H)**	**Weight**	**Price**
Piece	1 piece	15.5*13.2 *5.7 cm (6.1 × 5.2 × 2.2 inches)	20 g (0.04 lbs)	U$ 6.9
Box	8 pieces	25*16*15 cm (9.8× 6.3 × 5.9 inches)	320 g (0.7 lbs)	U$ 55
Case	96 pieces,12 boxes	53*45*36cm (20.9 × 17.7 × 14.2 inches)	5000 g (11.0 lbs)	U$ 660

About HealKEE MEDICAL

WE are offering Innovative Healthcare Environmental & Procedural Safety Solutions

- ***AirKEE ®*** *Portfolio (with FDA clearance, Class II medical device): one-stop, modular, mobile solutions to overcome the constrains of conventional renovation, to convert general environments to three critical healthcare settings including:*

  - ***PE*** *(Protective Environment for immunocompromised patients, HSCT/ICU etc.,)*
  - ***AII*** *(Aerosol Infection Isolation, infectious patients, Aerosol Generating Procedure)*
  - ***OT*** *(Operating Theatre, up to ISO 5 cleaning level)*

- ***AeroKEE ™*** *Series (Class I medical device): single-use procedural barriers designed to support exposure management during aerosol-generating endoscopic procedures.*

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Version: HL_BR_ARO_Dec 2025