

# AeroKEE™

## Single-Use Colonoscopy Pants

### Instructions for Use

**REF** HL-AERO-C-1  
**ARTG** 523280  
**Class** Medical Device Class I  
**Doc No.** HL-IFU-AERO-C-2-AU  
**Rev.** 02 | 2026-04-17  
**GMDN** 63872

**Manufacturer**  
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**ARTG Identifier: 523280 | ARTG Start Date: 10/02/2026**

### 1. INTENDED USE

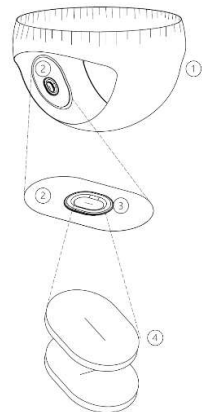
The AeroKEE™ Single-Use Colonoscopy Pants is intended to be worn by colonoscopy patients to help manage procedural fluids, support patient privacy, and improve workflow hygiene during the procedure.

<b>Intended User</b>	Healthcare professionals trained in colonoscopy procedure, or patients under their direction
<b>Patient Population</b>	For use on colonoscopy 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 apply over open wounds, broken skin, severe irritation, or areas requiring immediate clinical access.
- Remove or adjust if the product interferes with endoscope insertion, patient positioning, emergency access, tissue specimen retrieval, or therapeutic accessories.
- Not an incontinence garment; does not replace standard PPE 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



- Elastic Pants** Garment-like layer worn as directed; supports patient privacy and localized fluid management.
- Clear Panel** Transparent window for visual monitoring of the insertion area.
- Insertion Port** ~18 × 28 mm; fits commonly used compatible colonoscopes. Smooth interface reduces risk of scope surface abrasion.
- Sponge Interface** Dual-layer sponge with central slit; supports colonoscope insertion/withdrawal and localized fluid management.

### 4. MATERIALS AND LATEX STATEMENT

- Patient-contacting materials include: non-woven fabric.
- This product is not made with natural rubber latex.

### 5. DIRECTIONS FOR USE

### 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 or use between patients.
- Discontinue use if discomfort, skin irritation, allergic reaction, or procedural interference occurs.
- Do not use if packaging is damaged or product is visibly contaminated.
- Keep out of reach of children. Do not allow use outside a clinical procedure or without healthcare professional direction.

### 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-C-1
<b>Carton</b>	96 pcs (12×8)	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

**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 pants from packaging and inspect for damage.
2. Have the patient wear the pants as directed by healthcare staff, with the clear panel and insertion port correctly aligned with the colonoscope insertion area.
3. Ensure a comfortable fit around the waist and legs without restricting patient positioning or clinical access.
4. Confirm the product is suitable for the planned procedure and does not interfere with procedural access.
5. Confirm patient comfort and that access for colonoscope insertion, emergency access, tissue specimen retrieval, and therapeutic accessories is not compromised.
6. Insert the colonoscope through the sponge-opening interface and proceed per facility protocol and the colonoscope manufacturer's IFU.

**During the procedure**

Monitor the patient throughout; discontinue use or remove/adjust the product if discomfort, interference with the procedure, or an adverse reaction occurs.

**Removal and disposal**

Remove the pants carefully and clean the patient's body surfaces as required. Dispose of as clinical waste per facility procedures and applicable Australian state/territory requirements.

	Single use only
	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 colonoscope manufacturer's instructions, or facility protocols.

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