IFU Instructions for use – Do Not Discard

GV Health

Manufacturer name	GV Health Ltd
Manufacturer address	Hall House, 2 Arlington Court, Whittle Way, Arlington Business Park, Stevenage, Hertfordshire, SG1 2FS, UK
Product Name	Polycare®
Unique Identifier	IFU-GVH-20250923-001
Product type	Single use aprons, non-sterile Single use tabards, non-sterile.
Model identification	AOR4616, APW272, APB114, APY110, APG109, APP112, APR108, APW079, APG078, APG069, BTB000
Intended Use	Polycare single-use aprons and tabards are non-invasive devices/garments intended by the manufacturer to be used in the prevention of disease, by reducing the spread of microorganisms during patient examinations. The device provides basic barrier protection to both user and patient for use in clinical environments. It is worn for transient use (normally intended for continuous use for less than 60 minutes) and is not designed to come into prolonged contact with the patient or healthcare provider's skin, but rather to lay against existing clothing.
Device Description	Coloured polyethylene sleeveless garment. Unisex. Single-use devices available as aprons and tabards in various colours (green, orange, red, blue, clear, yellow, white, pink). The devices are manufactured from a blend of HDPE, LDPE, LLDPE, additives and colour pigments, with some variants containing recycled polyethylene and optional oxo-biodegradable additives (≤2% total composition). Available in dispenser boxes or continuous rolls with perforations. **Dimensions vary by product code:** ● Standard aprons: 1170mm length × 686mm width with 450mm tie length ● Larger variants: up to 1498mm length × 869mm width ● Tabards: 620mm × 550mm ● Gauge thickness: 16-45 microns depending on variant
Warnings and Precautions	**Warnings:** ● **Do not use in replacement of complex PPE** ● Device is **not resistant to chemicals** ● **Do not use if packaging is damaged** ● This device is **not PPE** and should not be used in replacement of PPE where the user suspects a high-risk interaction (e.g., Ebola infection or contact/interaction with hazardous materials such as cytotoxic drugs) **Precautions:** ● **Single-use only** - This device should not be re-used ● Use of this device does not discharge the user from their responsibility to **dispose of this device between uses** ● **Non-latex material** (suitable for users with latex allergies)
Preparation	1. Check packaging integrity - do not use if package is damaged or opened 2. Remove device from dispenser box or tear along perforations if using roll format 3. Ensure hands are clean before handling
Application	1. Place the device over the head using the neck opening 2. Ensure the device lies flat against existing clothing (not direct skin contact) 3. Secure the integral side ties around the midriff to fit properly 4. Ensure device provides adequate coverage for the intended examination/procedure 5. Use for transient periods only (less than 60 minutes continuous use)
Maintenance and Cleaning	● **No maintenance or cleaning required** - single-use device only ● **Do not attempt to clean, disinfect, or sterilize** for reuse ● **Dispose immediately after use** in accordance with local healthcare waste regulations
Storage Conditions	● **Protect from sunlight** (keep away from direct light sources) ● **Keep dry** (protect from moisture) ● **Observe temperature limits** as indicated on packaging ● **Use by expiry date** shown on packaging ● Store in original packaging until use
Disposal Instructions	**Safe Disposal of Device** ● Single-use only - This device must NOT be reused under any circumstances ● Dispose immediately after use - Remove and dispose of the device immediately following the procedure or examination ● Clinical waste classification - Used devices may be contaminated with bodily fluids and should be treated as clinical/infectious waste **Disposal Process** 1. Remove device carefully - Avoid contact with potentially contaminated surfaces 2. Place directly into appropriate clinical waste container - Use yellow clinical waste bags or containers as per local healthcare facility protocols 3. Wash hands thoroughly after disposal 4. Do not attempt to clean or disinfect for reuse
Troubleshooting	**Problem** / **Possible Cause** / **Solution** **Device tears during application** — Excessive force or sharp objects — Use gentle handling; inspect for sharp jewellery/objects **Poor fit** — Wrong size variant — Ensure correct product code selection for intended use **Ties break** — Overtightening — Apply moderate tension only when securing **Package damaged** — Storage/transport damage — Use alternative undamaged package; report to supplier
Incident and Complaints	**Report any serious incidents** that have occurred in relation to the device to: **Manufacturer:** GV Health Ltd. Hall House, 2 Arlington Court, Whittle Way, Arlington Business Park Stevenage, Hertfordshire, SG1 2FS, UK Email: info@gvhealth.com Telephone: +44 (0)1438 731 313 **Also report to the competent authority** of the Member State in which you are established in accordance with local incident reporting requirements. For any complaints about device performance, quality issues, or adverse events, contact GV Health using the above details with: ● Product code and batch number ● Description of the issue ● Date and circumstances of occurrence ● Any relevant photographs or documentation
Date and version control	23 Sept 2025 Version 1, Rev.1.0