

GENERAL DESCRIPTION

STERIS Barrier Product Solutions (BPS) offers custom cleanroom apparel packs designed to support and streamline the gowning procedures of pharmaceutical cleanrooms. A typical apparel pack contains a hood, face mask, coveralls, and boots. BPS cleanroom apparel packs can be customized to meet the unique gowning requirements of any facility. Customization options include:

- **Contents:** Items can be added or removed. For example, sleeves could be added to an apparel pack, or the boots could be removed and packaged separately. Sizes of gowning materials can be specified as needed.
- **Configuration:** How each item is folded, the order in which the items are presented, and the wrapping/packaging method for the apparel pack can be customized to facilitate aseptic donning. Single or double pouching within STERIS sterilization pouches with clean-peel feature is an option as well.
- **Sterilization:** All cleanroom apparel packs are available non-sterile or sterile (via ethylene oxide or gamma irradiation).

Most cleanroom apparel items are made of Tyvek^{®1} non-woven spunbonded olefin material. This fabric-like material is low linting, tear resistant, breathable, and an effective barrier against particles and microorganisms, thereby providing both protection of the cleanroom environment and comfort for cleanroom personnel.

APPAREL ITEMS

Item	Description
Hood	Material: Tyvek non-woven spunbonded olefin material
	Opening options: Full face, diamond shaped, eyes only
Face mask	Style: Pleat-style
	Fastener options: Ties, ear loops, elastic bands
	Side extensions: To expand the coverage provided by the face mask, side extensions made of Tyvek material can be added
	Anti-fog options: Adhesive strip or metal nose piece without adhesive
Coveralls	Material: Tyvek non-woven spunbonded olefin material
	Style options: Elastic neck and elastic wrists; elastic wrists and elastic ankles; custom styles (elastic can be added at the waist or ankles, collars can be added)
Boots	Material: Tyvek non-woven spunbonded olefin material
	Soles options: PVC, enhanced skid-resistant PVC
	Style: High top, elastic opening, elastic ankles or ankle ties
Other	BPS offers a range of additional apparel items including sleeves, lab coat and bunny suits (coveralls with attached hood and boots) made from Tyvek material. Hoods, coveralls, face masks, and boots are also available individually.

APPLICATIONS AND USAGE

All items within a cleanroom apparel pack are first wrapped in a sheet of Tyvek material and then packaged within a Tyvek/film clean-peel pouch. This ensures a sterile barrier during transport and storage and facilitates aseptic presentation of the contents in the gowning room. Double pouching is also available for further protection.

1 Tyvek is a registered trademark of DuPont or its affiliates.



Figure 1. Unopened cleanroom apparel pack (Tyvek side)



Figure 2. Unopened cleanroom apparel pack (film side)



Figure 3. Example of an opened pack, contents on the sterile field



Figure 4. Example of contents (boots, folded gown, hood, mask)

MATERIAL PROPERTIES

For most items made from Tyvek fabric:

Fabric Property	Test Method	Typical Result	Units
Basis Weight	ASTM D3776	1.22	oz/ld ²
Burst Strength – Mullen	ASTM D774	54	psi
Breaking Strength – Grab (MD)	ASTM D5034	18	lb _f
Breaking Strength – Grab (CD)	ASTM D5034	23	lb _f
Hydrostatic Head	AATCC 127	91	cm H ₂ O
Surface Resistivity (25°C and 55% RH)	ASTM D257	<6.3 x 10 ⁹	ohms/square
Bacterial Filtration Efficiency (3.0 µm)	ASTM F2101	99.0	%

For most face mask options:

Physical Property	Typical Result
Bacterial filtration efficiency (@3 µm)	≥95%
Particle filtration efficiency (@0.1 µm)	≥95%
Differential pressure	<5.0 mm H ₂ O/cm ²

STORAGE

Cleanroom apparel packs should be stored under cool and dry conditions.

SERVICE

Backed by over 100 years of expertise in sterilization and contamination control, STERIS offers consultation and evaluation of facility operations to ensure the appropriate products are selected. From process improvements to validation methodologies, STERIS stands ready to provide technical support to optimize facility performance. STERIS also has a fully staffed and equipped technical service laboratory to perform testing and provide troubleshooting support when needed.

For further information, please contact:



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