

GENERAL DESCRIPTION

Specialty cleanroom apparel and apparel packs from STERIS are designed to support and streamline the gowning procedures of pharmaceutical cleanrooms. A typical apparel pack contains a hood, face mask, coveralls, and boots. STERIS 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 DuPont™ 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. The items are packaged within a rigid Tyvek and Mylar film pouch that has a thickness of 2.35-2.50 mil.

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, pouch-style
	Fastener options: Ties, ear loops, elastic head straps
	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, film strip
Coveralls	Material: Tyvek® non-woven spunbonded olefin material
	Style options: Elastic wrists and elastic ankles; custom styles (elastic waist, snaps for boots, etc.)
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
Sleeves	Material: Tyvek® non-woven spunbonded olefin material
	Options: Length, thumbholes
Other	Additional items such as goggles, shoe covers, lab coats, and bunny suits are also available. All items are available individually or in a pack.

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 DuPont™ and Tyvek® are trademarks or registered trademarks of affiliates of DuPont de Nemours, Inc.



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/yd 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 × 10 ⁹	ohms/square
Bacterial Filtration Efficiency (3.0 µm)	ASTM F2101	99.0	%

* RH = relative humidity

For most face mask options:

Physical Property	Typical Result
Bacterial filtration efficiency (@3 µm)	≥95%
Particle filtration efficiency (@0.1 µm)	≥95%

STORAGE AND SHELF LIFE

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

Expiration date for all products: The expiration date is printed on the label and is 36 months from the date of manufacture.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

For further information, please contact:



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