

BioClean-D Sterile Sleeve Cover

BIOCLEAN-D™
 SLEEVE COVERS
 Sterile
S-BDSC-L

About

Offering exceptional comfort and protection, single use BioClean-D™ Sterile Disposable Sleeve Covers are constructed from antistatic low-linting CleanTough™ material, and feature elasticated upper arms and cuffs. The 'one size fits' all cover has been tailored for quick and simple donning.

**EXCEPTIONAL
 COMFORT &
 PROTECTION**

PPE CAT 3 TYPE PB [6]

ANTISTATIC

**LOW-LINTING &
 DURABLE**

Specifications

MATERIAL:

Antistatic CleanTough™ material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Antistatic to EN 1149-1 & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Class A

STERILIZATION:

Gamma irradiation

Features

- Extra long length 500mm
- Exceptional antistatic properties
- Low-linting
- Durable CleanTough™ material
- Tested against permeation standard ASTM D6978-05



Billy BioClean™ represents BioClean's™ GMP compatible disposable garments



Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Tested against standard EN ISO 13034 protective clothing against liquid chemicals (Type PB[6])
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standard EN 1149-1 protective clothing - electrostatic properties
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment
- Sterilized in accordance with ISO 11137-1:2006

Sterilization

Method: Gamma irradiation
 Minimum Dose: 25kGy Sterility
 Assurance Level: 10⁻⁶

Shelf Life & Storage

Three (3) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Performance Test Results

TEST	RESULT		PERFORMANCE CLASS (EN 14325)
Abrasion Resistance	10 to 100 cycles		1
Flex Cracking Resistance	5,000 to 15,000 cycles		3
Trapezoidal Tear Resistance	CD 29.5 N		2
Trapezoidal Tear Resistance	MD 50.8 N		3
Tensile Strength	MD 79.3 N		2
Tensile Strength	CD 59.4 N		1
Puncture Resistance	5.9 N		2
Repellence to Liquids	30% H ₂ SO ₄	96.9%	3
	10% NaOH	98.0%	3
	O-Xylene	94.6%	2
	Butan-1-ol	95.4%	3
Penetration by Liquids	30% H ₂ SO ₄	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Resistance to Ignition	Pass		N/A
Seam Strength ¹	103.2 N		3
Surface Resistivity	1.1 x 10 ¹⁰ Ω		N/A

¹Seam not destroyed.



CleanTough™ Material - ASTM D6978-05 Test Results

Breakthrough detection time (minutes)

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO-RUBICIN HYDRO- CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

