

BIOCLEAN-D SLEEVE COVERS Sterile S-BDSC-L

About

Offering comfort, protection and quick and simple donning, the single use BioClean-D Sterile Disposable Sleeve Covers are constructed from anti-static lightweight low-linting CleanTough material, featuring elasticated openings for a firm fit.

Specifications

MATERIAL:

Anti-static BioClean-D CleanTough white material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Anti-static to EN 1149-5* & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Class A

STERILIZATION:

Gamma irradiation

PPE CAT 3 TYPE PB [6]

ANTI-STATIC

LOW-LINTING

Features

- Extra long length 500mm
- Excellent ESD Properties
- Lightweight & low-linting
- Silicone-free



Ansell

Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Personal Protective Equipment PPE Regulation (EU)2016/425
- Tested against standard EN ISO 13034:2005+A1:2009 protective clothing against liquid chemicals (Type PB[6])
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standards: EN 1149-5:2008*, protective clothing - electrostatic properties; EN 530, Abrasion resistance; EN 7854, Flex cracking resistance; EN 6530, Resistance to penetration by liquids; EN 13934-1, Tensile strength; EN 9073-4, Trapezoidal tear resistance; EN 863, Puncture resistance; and EN 13935-2, Seam strength
- Processed in an NEBB certified ISO Class 4 environment
- Tested against permeation standard ASTM F739-12
- 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 – BioClean-D CleanTough White Material

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 29.3 N		2
Trapezoidal Tear Resistance	MD 55.5 N		3
Tensile Strength	CD 48 N		1
Tensile Strength	MD 97 N		2
Puncture Resistance	8 N		1
Repellence to Liquids	30% H ₂ SO ₄	96.3%	3
	10% NaOH	97.6%	3
	O-Xylene	95.7%	2
	Butan-1-ol	96.6%	3
Penetration by Liquids	30% H ₂ SO ₄	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Seam Strength ¹	70 N		2
Electrostatic Charge Half Decay Time, t_{50} (secs)	0.07		PASS

¹Seam not destroyed.



Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<260	Category I

BioClean-D™ CleanTough White Material - ASTM F739-12 Test Method Results

Mean Breakthrough Time (MBT), Minutes

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 µg/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO- RUBICIN HYDRO- CHLORIDE	5- FLURO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>042	<6	217 (275,162,215)	>240	>240	>240	>240	<10	30 (28,30,33)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

TO ORDER

Re-Order	Chest	Height	Size
S-BDSC-L	N/A	N/A	Universal

Packing

One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)

*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, are ideal for use in a static-safe environment.