



# BioClean-D™ Sleeve Covers - Sterile S-BDSC-L

## Sleeve Covers - Sterile

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

Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.

### Key Features and Benefits

- Long length min. 480mm
- Excellent ESD Properties
- Lightweight & low-linting



### Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing





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## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

<b>Material</b>	CleanTough™
<b>Audit Standards</b>	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
<b>Standards</b>	ASTM F739, CE 0598, EN 1149-5:2008, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013, EN ISO 14325, ISO 11137-1:2006, Category III, EN 13034:2005 + A1:2009
<b>Packaging Overview</b>	One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)
<b>Country Of Origin</b>	Sri Lanka
<b>Sterilization Method</b>	GAMMA irradiation (25 kGy)
<b>Sterilization Minimum Dose</b>	25kGy
<b>Sterility Assurance Level</b>	10 <sup>-6</sup>
<b>Cleanroom Class</b>	Class 10/ISO 4 & EU GMP Grade A
<b>Shelf Life</b>	Three (3) years from date of manufacture
<b>Construction</b>	Bound seams with single needle stitching
<b>Characteristics</b>	*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, and so are ideal for use in a static-safe environment.

### MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Flex Cracking Resistance	5,000 to 15,000 cycles	3
Trapezoidal Tear Resistance Cross Direction (CD)	CD 29.3 N	2
Trapezoidal Tear Resistance Machine Direction (MD)	MD 55.5 N	3
Tensile Strength Cross Direction (CD)	CD 48 N	1
Tensile Strength Machine Direction (MD)	MD 97 N	2
Puncture Resistance	8 N	1
Repellence to Liquids - 30% H <sub>2</sub> SO <sub>4</sub>	96.3%	3
Repellence to Liquids - 10% NaOH	97.6%	3
Repellence to Liquids - O-Xylene	95.7%	2
Repellence to Liquids - Butan-1-ol	96.6%	3
Penetration by Liquids - 30% H <sub>2</sub> SO <sub>4</sub>	0%	3
Penetration by Liquids - 10% NaOH	0%	3
Penetration by Liquids - O-Xylene	0%	3
Penetration by Liquids - Butan-1-ol	0%	3
Seam Strength <sup>2</sup>	70 N	2
Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs)	0.07	PASS

- 1.
2. Seam not destroyed



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## PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5Qm (counts/min) <260

## ASTM F739-12 TEST METHOD RESULTS

DRUG	Mean Breakthrough Time (MBT), Minutes Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 Qg/cm <sup>2</sup> /min
CISPLATIN	>240
CARMUSTINE	<6
CYCLOPHOSHAMIDE	217 (275,162,215)
DOXORUBICINHYDROCHLORIDE	>240
5-FLUOROURACIL	>240
METHOTREXATE	>240
ETOPOSIDE	>240
PACLITAXEL	<10
THIOTEPA	30 (28,30,33)

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

## SIZE CHART

Universal long length min. 480mm

For additional information visit us at [www.ansell.com](http://www.ansell.com), or call us at

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## Performance Standards and Regulatory Compliance



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Please see product validation pack or contact Ansell customer service for specific data on use of garments with cytotoxic drugs. Garments used for protection against such drugs must be selected specifically for the type of chemicals used.

