



## BioClean-C™ Sleeve Covers - Sterile S-BCSC

# Sterile cleanroom sleeve covers for protection against chemotherapy drugs

- **Optimized protection:** BioClean™ chemotherapy-protective sleeve covers are specially developed to protect against a range of chemotherapy drugs, with ultrasonically bonded seams and protective tape, for added security
- **Guaranteed cleanliness:** These chemotherapy-protective sleeves are constructed from sterile CleanTough™ material that is lightweight and low-linting
- **Assured barrier protection:** BioClean-C™ chemotherapy-protective sleeve covers have been tested against ASTM F739-12 permeation standards
- **Maximized practicality:** These one-size-fits-all sterile sleeve covers are tailored for quick and simple donning
- **Reduced contamination risks:** They are specially packaged to eliminate cross contamination and sterilized using gamma irradiation to yield a minimum SAL of  $10^{-6}$



### Key Features and Benefits

- **Ultrasonically bonded seam:** For sleeve covers that deliver a secure fit
- **Lightweight, low-linting CleanTough™ fabric:** Comfort and durability
- **ASTM F739-12 compliance:** For assured permeation protection

### Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Laboratory and Research





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## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

Material	CleanTough™
Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Standards	ASTM F739, CE 0598, EN 13935-2, EN ISO 14325, EN 14605:2005 + A1:2009, EN ISO 13688:2013+A1:2021, Partial Body Protection Only, Category III, EN 13034:2005 + A1:2009
Storage	Store in a dry cool place 40°C away from direct sunlight and fluorescent light.
Country Of Origin	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture.
Construction	Ultrasonically bonded seams covered with protective tape
Characteristics	Low particulating

### PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5µm (counts/min) <1700

### 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 µg/cm <sup>2</sup> /min
CISPLATIN	>480
CARMUSTINE	>480
CYCLOPHOSAMIDE	>480
DOXORUBICINHYDROCHLORIDE	>480
5-FLUOROURACIL	>480
METHOTREXATE	>480
ETOPOSIDE	>480
PACLITAXEL	>480
THIOTEPA	>456

Results achieved under controlled laboratory conditions, by accredited external testing laboratory. \*For Bioclean D and Bioclean 2000, the chemical permeation results relates to the fabric performance for reference only. Seams and closures may have lower breakthrough times. We recommend garments with sealed seams such as Bioclean-C to be worn over the coverall for added protection against chemotherapy drugs handling.

### SIZE CHART

S-BCSC; Size: Universal



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## MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS	PERFORMANCE STANDARD
Abrasion Resistance	>10 cycles	1	EN 12947-2
Puncture Resistance	>5 N	1	ISO 13996
Trapezoidal Tear Resistance Cross Direction (CD)	>10 N	1	EN ISO 9073-4
Trapezoidal Tear Resistance Machine Direction (MD)	>10 N	1	EN ISO 9073-4
Tensile Strength Cross Direction (CD)	>30 N	1	EN ISO 13934-1
Tensile Strength Machine Direction (MD)	>30 N	1	EN ISO 13934-1
Repellence to Liquids – 30% H <sub>2</sub> SO <sub>4</sub>	>90%	3	ISO 6530
Repellence to Liquids – 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids – O-Xylene	>90%	3	ISO 6530
Repellence to Liquids – Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids – 30% H <sub>2</sub> SO <sub>4</sub>	<1%	3	ISO 6530
Penetration by Liquids – 10% NaOH	<1%	3	ISO 6530
Penetration by Liquids – O-Xylene	<1%	3	ISO 6530
Penetration by Liquids – Butan-1-ol	<1%	3	ISO 6530
Seam Strength <sup>1</sup>	>50 N	2	ISO 13935-2

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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.

