



# 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<sup>-6</sup>



### 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

<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 13034:2005 + A1:2009, EN 13935-2, EN ISO 14325, EN 14605:2005 + A1:2009, EN ISO 13688:2013, EN ISO 13688:2013+A1:2021, Category III, EN 13034:2005 + A1:2009
<b>Country Of Origin</b>	China
<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>	Ultrasonically bonded seams covered with protective tape
<b>Characteristics</b>	Low particulating

### MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Trapezoidal Tear Resistance Cross Direction (CD)	CD 32.3 N	2
Trapezoidal Tear Resistance Machine Direction (MD)	MD 50.6 N	3
Tensile Strength Cross Direction (CD)	CD 47 N	1
Tensile Strength Machine Direction (MD)	MD 94 N	2
Puncture Resistance	10 N	1
Repellence to Liquids - 30% H <sub>2</sub> SO <sub>4</sub>	99.0%	3
Repellence to Liquids - 10% NaOH	98.4%	3
Repellence to Liquids - O-Xylene	91.4%	1
Repellence to Liquids - Butan-1-ol	93.9%	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>1</sup>	74 N	2

1. Seam not destroyed



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## PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5Qm (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 Qg/cm <sup>2</sup> /min
CISPLATIN	>240
CARMUSTINE	>240
CYCLOPHOSHAMIDE	>240
DOXORUBICINHYDROCHLORIDE	>240
5-FLUOROURACIL	>240
METHOTREXATE	>240
ETOPOSIDE	<6
PACLITAXEL	>240
THIOTEPA	55 (46,88,31)

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

## SIZE CHART

S-BCSC; Size: Universal

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

CE 0598



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