

### BioClean-C<sup>™</sup> 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 lowlinting
- Assured barrier protection: BioClean-C<sup>™</sup> chemotherapy-protective sleeve covers have been tested against ASTM F739-12 permeation standards
- Maximized practicality: These one-sizefits-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
- 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, EN 13935-2, EN ISO 14325, EN ISO 13688:2013, Category III, EN 13034:2005 + A1:2009
Country Of Origin	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10-6
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

### **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

<sup>1.</sup> Seam not destroyed





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

#### 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/cm2 /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

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**Performance Standards and Regulatory Compliance** 



