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}
- **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_2SO_4	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_2SO_4	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[1]	74 N	2

1. Seam not destroyed

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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/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

EN 13034:2005 + A1:2009
TYPE PB[6]

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