BioClean-C™ Sleeve Covers BCSC

Non-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 garments are constructed from CleanTough™ material that is both 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
- **Secure fit**: An integrated thumb loop keeps the sleeve from rolling back and exposing the arm or wrist.

Key Features and Benefits

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

Industries

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

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TECHNICAL DATA SHEET

PRODUCT INFORMATION

Material	Polyethylene/ non-woven polypropylene laminate
Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Standards	ASTM F739, CE 0598, EN 13034:2005 + A1:2009, EN 13935-2, EN ISO 14325, Partial Body Protection Only, Category III, EN 14605:2005 + A1:2009, UKCA
Packaging Overview	• 30 pieces per sealed inner PE bag; 1 inner bags per sealed outer PE bag; 6 outer bags per lined carton (180 pieces)
Storage	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Cleanroom Class	Class 10/ISO 4
Shelf Life	5 years
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/cm2 /min
CISPLATIN	>480
CARMUSTINE	>480
CYCLOPHOSHAMIDE	>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

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)	EN ISO 9073-4	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% H₂SO₄	>90%	3	ISO 6530
Repellence to Liquids – 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids – O-Xylene	>80%	2	ISO 6530
Repellence to Liquids – Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids – 30% H₂SO₄	<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[1]	>50 N	2	ISO 13935-2

ORDERING INFORMATION

	SIZE	BioClean-C Chemo Sleeve Covers BCSC
BCSC	REORDER NO.	BCSC

Performance Standards and Regulatory Compliance

CE 0598 TYPE PB [6] PARTIAL BODY PROTECTION ONLY EN 14605:2005 +A1:2009 TYPE PB4

UK CA

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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.