



## 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 | <ul style="list-style-type: none"><li>30 pieces per sealed inner PE bag; 1 inner bags per sealed outer PE bag; 6 outer bags per lined carton (180 pieces)</li></ul>                                                                                                                                                                                            |
| 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) | $\geq 0.5Q_m$ (counts/min) <1700 |

### ASTM F739-12 TEST METHOD RESULTS

| DRUG                     | Mean Breakthrough Time (MBT), Minutes<br>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                | >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

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% H <sub>2</sub> O <sub>2</sub>  | >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% H <sub>2</sub> O <sub>2</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          |

## ORDERING INFORMATION

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

### Performance Standards and Regulatory Compliance



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