



# 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>
- **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 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                   | {EB3FC5C8-9B74-43B1-9DE4-155A75700CB8}                                                                                                                                                                                                                                                                                                                         |
| Audit Standards            | Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D                                                                                                                                                                                                                                                                                   |
| Standards                  | ASTM F739, CE 0598, EN 13935-2, EN ISO 14325, EN 14605:2005 + A1:2009, EN ISO 13688:2013+A1:2021, Partial Body Protection Only, Category III, UKCA                                                                                                                                                                                                             |
| Packaging Overview         | <ul style="list-style-type: none"><li>One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; 6 outer bags per lined carton (90 pairs)</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. |
| Sterilization Method       | GAMMA irradiation (25 kGy)                                                                                                                                                                                                                                                                                                                                     |
| Sterilization Minimum Dose | 25kGy                                                                                                                                                                                                                                                                                                                                                          |
| Sterility Assurance Level  | 10 <sup>-6</sup>                                                                                                                                                                                                                                                                                                                                               |
| Cleanroom Class            | Class 10/ISO 4;EU GMP Grade A                                                                                                                                                                                                                                                                                                                                  |
| Shelf Life                 | 3 years                                                                                                                                                                                                                                                                                                                                                        |
| Construction               | Ultrasonically bonded seams covered with protective tape                                                                                                                                                                                                                                                                                                       |
| Characteristics            | Low particulating                                                                                                                                                                                                                                                                                                                                              |

### 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<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

S-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 Sleeve Covers - Sterile S-BCSC |
|--------|-------------|-------------------------------------------|
| S BCSC | REORDER NO. | S-BCSC                                    |

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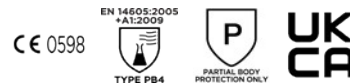
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## Performance Standards and Regulatory Compliance



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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.

