

BioClean-C Sterile Chemotherapy Protective Sleeve Covers

S-BCSC

About

Designed for protection, the BioClean-C™ Sterile Chemotherapy Protective Sleeve Covers have been specially developed for maximum protection against a range of chemotherapy drugs and to be compatible with ISO Class 4 cleanrooms. Constructed from lightweight, low-linting and hard wearing CleanTough™ material, the sleeve covers feature elasticated arms and 100% polyester elasticated cuffs. The 'one size fits all' cover has been tailored for quick and simple donning.

Specifications

MATERIAL:
 CleanTough™ material

COLOUR:
 Blue

CONSTRUCTION:
 Ultrasonically bonded seams covered with protective tape

CLASSIFICATION:
 PPE Cat 3 Type PB [6]

CHARACTERISTICS:
 Low particulating

COMPATIBILITY:
 ISO Class 4

STERILIZATION:
 Gamma irradiation

Features

- Tested against ASTM D6978-05 using a minimum of nine cytotoxic drugs
- Ultrasonically bonded seams with protective tape
- Elasticated for secure fit
 Processed to ensure ISO Class 4 compatibility
- 100% polyester elasticated cuffs
- Lightweight, low-linting & hard wearing CleanTough™ material

LIGHTWEIGHT & LOW-LINTING

**TESTED AGAINST
 ASTM D6978-05**

**100% POLYESTER
 ELASTICATED CUFFS**

**ULTRASONICALLY
 BONDED SEAMS**



Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Tested against standard EN ISO 13034 protective clothing against liquid chemicals (Type PB [6])
- Tested against standard EN 14325 protective clothing against chemicals
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment
- Sterilized in accordance with ISO 11137-1:2006

Sterilization

Method: Gamma irradiation Minimum
 Dose: 25kGy Sterility Assurance Level:
 10⁻⁶

Shelf Life & Storage

Three (3) years from date of
 manufacture. Store in a dry, cool place
 (<40°C) away from direct sunlight and
 fluorescent light.

Performance Test Results

TEST	RESULT		PERFORMANCE CLASS (EN 14325)
Abrasion Resistance	10 to 100 cycles		1
Flex Cracking Resistance	5,000 to 15,000 cycles		3
Trapezoidal Tear Resistance	CD 42.5 N		3
Trapezoidal Tear Resistance	MD 58.4 N		3
Tensile Strength	MD 68 N		2
Tensile Strength	CD 43 N		1
Puncture Resistance	9 N		1
Repellence to Liquids	0% H ₂ SO ₄	99.0%	3
	10% NaOH	98.4%	3
	O-Xylene	91.4%	2
	Butan-1-ol	93.9%	2
Penetration by Liquids	30% H ₂ SO ₄	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Seam Strength ¹	90 N		3

Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<260	Category I

Physical Properties

PRODUCT CODE	SIZE	CHEST SIZE	HEIGHT
S-BCSC	Universal	N/A	N/A



CleanTough™ Material - ASTM D6978-05 Test Results

Breakthrough detection time (minutes)

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 $\mu\text{g}/\text{cm}^2/\text{min}$

CISPLATIN	CARMUSTINE	CYCLO-PHOSPHA-MIDE	DOXO-RUBICIN HYDRO-CHLORIDE	5-FLUORO-URACIL	METHO-TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

