

BIOCLEAN-C™ CHEMOTHERAPY Protective Sleeve Covers BCSC

About

Designed for protection, the BioClean-C™ 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

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

Shelf Life & Storage

Five (5) 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	MD 58.4 N		3
Trapezoidal Tear Resistance	CD 42.5 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

¹Seam not destroyed.

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
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 µg/cm²/min

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

TO ORDER

Re-Order	Chest	Height	Size
BCSC	N/A	N/A	Universal

Packing

30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; six outer bags per lined carton (180 pieces)

CONTACT

Europe (Headquarters)

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BioClean™ is a brand of Nitritex Ltd.

For more information, please visit www.bioclean.com

BCSC/1612/PDS23

BIOCLEAN-C™ CHEMOTHERAPY Sterile 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

LIGHTWEIGHT & LOW-LINTING

**TESTED AGAINST
ASTM D6978-05**

**100% POLYESTER
ELASTICATED CUFFS**

**ULTRASONICALLY
BONDED SEAMS**

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



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 µg/cm²/min

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

TO ORDER

Re-Order	Chest	Height	Size
S-BCSC	N/A	N/A	Universal

Packing

One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)

CONTACT

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S-BCSC/1611/PDS18