CARTER-HEALTH™
DISPOSABLES

BioClean-D™

BioClean-D Longer Length Overboots - Sterile S-BDOB-L

Overboots - Longer Length - Sterile

Offering exceptional comfort and protection, the single-use BioClean-D Sterile longer (height 500mm) Overboots are constructed from antistatic low-linting CleanTough material, and feature a slip resistant sole and easy tie-fastenings at the top and ankle.

Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.

- Longer length - 500mm
- Low-linting
- Tie-fastenings at top & ankle
- Slip-resistant sole

Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing

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TECHNICAL DATA SHEET

PRODUCT INFORMATION

	S-BDOB-L
Material	Polyethylene/non-woven polypropylene laminate
Color	White
Manufacturing/QMS Audit Standards	Manufacturing QMS Audit Standards ISO 9001 PPE Regulation 2016 425 Module D
Regulatory/Standards Compliance	ASTM F739, CE 0598, EN ISO 13688:2013, EN 1149-5:2008, EN 13934-1, EN 19935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 14325, ISO 11137-1:2006, Category III, EN 13034:2005 + A1:2009
Storage and packaging	30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; five outer bags per lined carton (150 pieces
Country of Origin	Malaysia
Available sizes	Universal
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10^{-6}
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture
Construction	Bound seams with single needle stitching
Characteristics	*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, and so are ideal for use in a static-safe environment.

MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Flex Cracking Resistance	2,500 to 5,000 cycles	3
Trapezoidal Tear Resistance Cross Direction (CD)	CD 29.3 N	2
Trapezoidal Tear Resistance Machine Direction (MD)	MD 55.5 N	3
Tensile Strength Cross Direction (CD)	CD 48 N	1
Tensile Strength Machine Direction (MD)	MD 97 N	2
Puncture Resistance	8 N	1
Repellence to Liquids – 30% H_2SO_4	96.3%	3
Repellence to Liquids – 10% NaOH	97.6%	3
Repellence to Liquids – O-Xylene	95.7%	2
Repellence to Liquids – Butan-1-ol	96.6%	3
Penetration by Liquids – 30% H_2SO_4	0%	3
Penetration by Liquids – 10% NaOH	0%	3
Penetration by Liquids – O-Xylene	0%	3
Penetration by Liquids – Butan-1-ol	0%	3
Seam Strength[2]	70 N	2
Electrostatic Charge Half Decay Time, t_{50} (secs)	0.07	PASS

1.
2. Seam not destroyed

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PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5µm (counts/min) <260

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	>240
CARMUSTINE	<6
CYCLOPHOSHAMIDE	217 (275,162,215)
DOXORUBICINHYDROCHLORIDE	>240
5-FLUOROURACIL	>240
METHOTREXATE	>240
ETOPOSIDE	>240
PACLITAXEL	<10
THIOTEPA	30 (28,30,33)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

SIZE CHART

Universal

Performance Standards and Regulatory Compliance

CE 0598 EN 1149-5:2008 ISO ISO 11137-1

TYPE PB [6]

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.