

## Overboots - Non-sterile

The single use BioClean-D Disposable Overboots are constructed from antistatic low-linting CleanTough material, and feature a slip-resistant sole and tie fastenings for quick and easy donning.

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

### Key Features and Benefits

- Lightweight & low-linting CleanTough material
- Elasticated opening for a firm fit
- Easy tie fastenings for a secure hold on leg
- Slip-resistant sole



### Industries

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





# BioClean-D™ Overboots BDOB

## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

<b>Material</b>	CleanTough™
<b>Audit Standards</b>	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
<b>Standards</b>	ASTM F739, CE 0598, EN ISO 13688:2013, EN 1149-5:2008, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 14325, Category III, EN 13034:2005 + A1:2009
<b>Packaging Overview</b>	30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; five outer bags per lined carton (150 pieces)
<b>Country Of Origin</b>	China
<b>Cleanroom Class</b>	Class 10/ISO 4
<b>Shelf Life</b>	Five (5) years from date of manufacture.
<b>Construction</b>	Bound seams with single needle stitching
<b>Characteristics</b>	*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	5,000 to 15,000 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 <sub>2</sub> SO <sub>4</sub>	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 <sub>2</sub> SO <sub>4</sub>	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 <sup>2</sup>	70 N	2
Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs)	0.07	PASS

- 1.
2. Seam not destroyed



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## PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5Qm (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 Qg/cm <sup>2</sup> /min
CISPLATIN	>240
CARMUSTINE	<6
CYCLOPHOSAMIDE	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

## ORDERING INFORMATION

	SIZE	Universal
BDOB	REORDER NO.	BDOB

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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.

