



ISO-MED

BioClean™

Fusion S-BFAP

Sterile Polychloroprene Cleanroom
Glove Compatible with Class 10 (ISO 4)
Environments

Ultra-clean, tactile sterile polychloroprene cleanroom glove with proven chemical protection



Neoprene

BioClean Fusion Sterile Polychloroprene Cleanroom Gloves contain no natural latex proteins, are comfortable and thin to reduce wearer fatigue and increase tactility. The Fusion is double-donnable and features a beaded cuff for strength.

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

- Increased tactility
- Powder-free & latex-free
- Beaded cuff for strength
- Non-particulating EasyTear packaging



Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Lab and R&D
- Sterile Processing Department

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TECHNICAL DATA SHEET

PRODUCT INFORMATION

Fusion S-BFAP	
Material	Neoprene (Polychloroprene)
Color	Green
Shape	Ambidextrous
Cuff	Beaded
Manufacturing/QMS Audit Standards	Manufacturing QMS Audit Standards ISO 9001 PPE Regulation 2016 425 Module D
Regulatory/Standards Compliance	CE 0598, EN 420:2003 + A1:2009, EN 421:2010, EN 455 Part 2, Food Contact, ISO 9001:2015, Category III
Packaging	One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)
Storage	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
Country of Origin	Malaysia
Available sizes	10, 5-5.5, 6-6.5, 9.0, 7-7.5, 8-8.5
Powder Content	Powder-Free
External Glove Surface	Textured Fingers
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 ⁻⁶
Cleanroom Compatibility	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Five (5) years from date of manufacture.
Tested for use with Chemotherapy Drugs	Yes
Protein Level	50 µg/g or less of total extractable protein

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PHYSICAL PROPERTIES

#PDS.DisposableGlove.Sizes#	Typical Values						Testing Method
	10	5-5.5	6-6.5	7-7.5	9	8-8.5	
Length (mm/in)	300 / 12						EN420
Palm Width	120/4.7	76/3	86/3.4	95/3.7	115/4.5	106/4.2	
Freedom from Holes	0.65 AQL Performance Level 3						EN 374-2
Typical Particle Count > 0.5µm (counts / cm ²)	850						IEST-RP-CC005.4
Minimum Single Wall Palm Thickness (mm/mil)	0.10 / 3.94						EN455-2
Minimum Single Wall Finger Thickness (mm/mil)	0.12 / 4.72						EN 455-2
Minimum Single Wall Cuff Thickness (mm/mil)	0.07/2.76						EN 455-2
During Ageing							
Force at Break (N)	≥ 9 N						EN 455-2

IONIC CONTENT

Concentration in µg/cm ²	Typical	Concentration in µg/cm ²	Typical
Ammonium	0.003	Nitrate	0.884
Bromide	Not Detected	Nitrite	Not Detected
Calcium	0.652	Phosphate	Not Detected
Chloride	0.194	Potassium	0.315
Fluoride	Not Detected	Sodium	0.099
Lithium	Not Detected	Sulphate	0.025
Magnesium	0.007	Zinc	Not Detected

ORDERING INFORMATION

	SIZE	10	5-5.5	6-6.5	7-7.5	9	8-8.5
Fusion S-BFAP	REORDER NO.	S-BFAP-1010	S-BFAP-5055	S-BFAP-6065	S-BFAP-7075	S-BFAP-9090	S-BFAP-8085

Performance Standards and Regulatory Compliance



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