BioClean™

Fusion S-BFAP

Sterile Disposable Neoprene
(Polychloroprene Cleanroom Glove)

Sterile polychloroprene cleanroom gloves, combining tactility and comfort

- **Assured comfort and tactility:** Easy to don and doff and ideal for double gloving, BioClean™ Fusion (Sterile) S-BFAP neoprene gloves' optimal thickness levels maintain comfort and tactility with prolonged use
- **Allergy protection:** As these powder-free disposable gloves are made from latex-free polymers, they eliminate Type I latex allergy risks
- **Enhanced cuff design:** Their beaded, extended-length cuff design combines a secure fit with additional arm coverage, boosting hand and wrist protection
- **Minimized contamination risks:** They come in non-particulating EasyTear packaging, reducing contamination risks in the cleanroom environment
- **CAUTION:** Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations

KEY FEATURES & BENEFITS

- **Optimal thickness:** Assured comfort and tactile sensitivity
- **Latex-free neoprene formulation:** Type I allergy risks eliminated
- **Extended beaded cuff design:** Enhanced hand protection

Industries

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

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TECHNICAL DATA SHEET

	Product Information
Material	Neoprene (Polychloroprene)
Color	Green
Shape	Ambidextrous
Cuff	Beaded
Manufacturing/QMS Audit Standards	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
Regulatory/Standard Compliance	CE 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA
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) **More sustainable packaging:** These sterile gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases. *Inner wrap, pouch, bag and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country of Origin	Indonesia
Available sizes	XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10), 2XL (10.5-11)
Powder Content	Powder-Free
External Glove Surface	Textured Fingers
Internal Glove Surface	Polymer Coated
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10^{-6}
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
Shelf Life	Five (5) years from date of manufacture.
Tested for use with Chemotherapy Drugs	Yes
Protein Level	N/A: contains no natural rubber latex
Anti-static	Yes

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Physical Properties							Testing Method
Sizes	XS (5.5 - 6)	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)	2XL (10.5-11)	EN 420
Typical Length (mm/in)	300 / 12						
Palm Width (mm/in)	76/3	86/3.4	95/3.7	106/4.2	115/4.5	120/4.7	
Freedom from Holes	1.5 AQL						EN 374-2
Typical Particle Count ≥0.5µm (counts / cm^2)	850						IEST-RP-CC005.4
Target Single Wall Palm Thickness (mm/mil)	0.10 / 3.94						EN 455-2
Target Single Wall Finger Thickness (mm/mil)	0.12 / 4.72						EN 455-2
Target Single Wall Cuff Thickness (mm/mil)	0.07/2.76						EN 455-2
Ultimate tensile strength (MPa) During Aging	Min. 14						ASTM D412-06a
Force at Break (N) During Aging	≥ 6 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	XS (5.5 - 6)	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)	2XL (10.5-11)
REORDER NO.	S-BFAP-5055	S-BFAP-6065	S-BFAP-7075	S-BFAP-8085	S-BFAP-9090	S-BFAP-1010

PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE

CE 0493 EN 421 EN ISO 374-1/Type C EN ISO 374-5 VIRUS UKCA

For additional information visit us at www.ansell.com, or call us at

Europe, Middle East & Africa Region
Ansell Healthcare Europe NV
T: +32 (0) 2 528 74 00
F: +32 (0) 2 528 74 01

Asia Pacific Region
Ansell Global Trading Center
T: +603 8310 6688
F: +603 8310 6699

North America Region
Ansell Healthcare Products LLC
US T: +1 800 800 0444
US F: +1 800 800 0445
CA T: +1-800-363-8340

Latin America & Caribbean Region
Ansell Commercial Mexico S.A. de C.V.
T: +52 442 248 1544 / 248 3133

Australia
Ansell Limited
T: +61 1800 337 041
F: +61 1800 803 578

UK
Ansell Nitritex
T: +44 1638 663338
F: +44 1638 668890

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