

New & Improved Stretchease Gloves

Powder-Free Nitrile Examination Gloves

Low Extractable Accelerator-Free

Approved for Use with Chemotherapy Drugs

Approved for Use with Fentanyl

This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole



Dimension

Thomas No.	Size	Palm Width (mm)	Length (mm)
1159G03-NI	Extra-Small	70 - 80	240 (min) / 9.5 inch
1159G04-NI	Small	81 - 90	240 (min) / 9.5 inch
1159G05-NI	Medium	91 - 100	240 (min) / 9.5 inch
1159G06-NI	Large	101 - 110	240 (min) / 9.5 inch
1159G07-NI	XL-Large	111 - 120	240 (min) / 9.5 inch
1159G13-NI	2XL-Large	>120	240 (min) / 9.5 inch

Design Feature	Ambidextrous, straight fingers, finger textured & beaded cuff
Product Conformance	FDA 510K Class 1 Compliant Conforms to ASTM D6319 & EN 455 Compliant with European Medical Device Directive 93/42/EEC (CE Class 1)
Packing	S-L: 100 gloves per dispenser box; 10 dispenser boxes per master carton XL-XXL: 90 gloves per dispenser box; 10 dispenser boxes per master carton

Material	100% Nitrile (Acrylonitrile-butadiene)
Appearance	Powder free, non-sterile
Color	Periwinkle blue
Surface	Textured Fingers

Thickness

Point of Thickness Measurements	Single Wall (mm)
Finger (at 15mm from the extreme tip)	0.10 (min.)" - 3.9 mil.
Palm (at center of palm)	0.07 (min.)" - 2.8 mil.

Physical Properties

Criteria	Before Aging	After Aging
Tensile Strength (MPa)	≥ 14	≥ 14
Elongation (%)	650 (min.)	600 (min.)
Force at Break (N)	≥ 6	≥ 6

Quality Assurance	Manufacturing process in compliance with ISO 9001 & ISO 13485 Quality Management System & ISO 14001 Environmental Management System.
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Chemical Testing: Permeation testing per ASTM D 6978-05

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)	Steady State Perm. Rate (Specimen 1/2/3) (µg/cm²/minute)
Carboplatin, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	24.0 (24.3, 24.0, 24.3)	0.4 (0.4, 0.4, 0.5)
Cisplatin 1.0 mg/ml (1,000 ppm)	90 - 100	N/A
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	100 - 110	N/A
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	110 - 120	N/A
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A
Mitoxantrone, 2.0 mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A
Thiotepa 10.0 mg/ml (10,000 ppm)	56.9 (56.9, 67.7, 69.3)	0.2 (0.3, 0.2, 0.2)
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A

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Chemical Testing: Permeation testing per ASTM D 6978

Test Drug and Concentration	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)	Steady State Perm. Rate (Specimen 1/2/3) (µg/cm ² /minute)
Fentanyl Citrate Injection, 100 mcg/2mL	No breakthrough up to 240 min.	N/A

Testing Conditions:

Standard Test Method Used: ASTM F 739

Chemical Tested	Average Breakthrough Detection Time (Sample 1,2,3) (Minutes)	Average Stanfardized Breakthrough Time (Sample 1,2,3) (Minutes)	Average Steady State Perm. Rate (Sample 1,2,3) (Minutes)	Other Observations
Acetic Acid, Glacial	6.3 (9,5,5)	9,7 (10.0,10.0,9.0)	1.1E ⁺⁰⁵ (1.3E ⁺⁰⁵ ,1.2E ⁺⁰⁴ ,1.1E ⁺⁰⁵)	Severe Swelling and degradation
Acrylamide, 40%	100 (100,100,100)	206.0 (217.3,193.4,207.4)	0.3 (0.3,0.3,0.2)	No significant changes
Ammonium Hydroxide, 30%	30 (30,30,30)	36.2 (34.8,41.0,32.8)	399 (494,459,244)	Slight swelling and no degradation
CaviCide	20 (20,20,20)	20 (20,20,20)	407.7 (381,434,408)	No significant changes
Chlorhexidine Gluconate, 4%	>480	>480	N/A	No significant changes
Cidex OPA	53.3 (40,60,60)	55.5 (42.4,62.6,61.4)	4.4 (4.6,4.1,4.6)	No significant changes
Ethidium Bromide, 10mg/ml	>480	>480	N/A	No significant changes
Formaldehyde, 37%	53.3 (60,40,60)	402.4 (247.3,>480, >480)	0.02 (0.02,0.02,0.01)	Slight swelling and no degradation
Glutaraldehyde, 50%	213.3 (220,240,180)	213.5 (220.2,240.2,180.2)	1.5 (1.6,1.2,1.7)	Slight swelling and no degradation
Hydrogen Peroxide, 30%	0 (0,0,0)	9 (3.3,21.4,2.3)	3.5 (4.0,4.0,2.4)	Slight swelling and no degradation
Instra-Clean Single Enzyme Solution	53.3 (60,60,40)	54.0 (60.6,60.6,40.7)	0.5 (0.6,0.4,0.5)	No significant changes
Isopropyl Alcohol, 70%	8 (8,8,8)	7.2 (17.6,17.1,16.9)	14.4 (19.0,13.7,10.6)	Moderate Swelling and degradation
Isopropyl Alcohol, 90%	8 (8,8,8)	10.6 (10.4,10.4,11.0)	18.9 (18.3,19.5,18.9)	Moderate Swelling and degradation
n-Hexane, 96%	8 (8,8,8)	9.1 (9.1,9.0,9.1)	33.4 (41.1,33.0,26.0)	Severe Swelling and degradation
Povidone Iodine, 10%	>480	>480	N/A	No significant changes
Sodium Hydroxide, 50%	>480	>480	N/A	No significant changes
Sodium Hypochlorite, 10-13%	>480	>480	N/A	No significant changes
Sulfuric Acid, 50%	>480	>480	N/A	No significant changes
Quaternary Cleaner	>480	>480	N/A	No significant changes

EN 16523-1:2015

Chemical tested	Breakthrough time (Mins)	Permeation performance level	Glove Marking Classification Type
Hydrogen peroxide 30%	Min 14 mins	Level 1 (> 10 mins)	Type C with a minimum of 1 chemical that must reach at least Level 1 permeation
Formaldehyde 37%	Min 180 mins	Level 6 (> 480 mins)	
n-Heptane	Min 89 mins	Level 3 (> 60mins)	

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