

## Sterile Polyisoprene Sensitive Powder-Free Non-Latex Surgical Gloves



- · Smooth Finish with Micro Roughened Surface
- Polymer Coating
- Anatomical Fit Hand Specific
- · Donnable on wet hands
- · Beaded Cuff
- Micro Thin For Improved Tactile Sensitivity and for ease of donning as an Underglove

**Material:** Synthetic Polyisoprene NOT MADE WITH NATURAL RUBBER LATEX

Powder Residue: POWDER FREE <2mg/glove

Color: Green

**Sterilization method :** Gamma Ray

PRODUCT CODE	SIZE	COLOR	PACKAGING
DOMPISENS-55	5.5		
DOMPISENS-60	6.0	GREEN	
DOMPISENS-65	6.5		1 walleted pair per pouch, 50 pouches per dispenser box, 4 boxes per case
DOMPISENS-70	7.0		
DOMPISENS-75	7.5		
DOMPISENS-80	8.0		
DOMPISENS-85	8.5		
DOMPISENS-90	9.0		

**SHELF LIFE/EXPIRATION:** 5 years (60 months from date of manufacture) Expiration date is printed on packaging.

## STANDARDS:

ASTM D3577 / ASTM D6978-05 EN455 / EN420 / EN374 / EN16523

### APPROVAL:

FDA 510k Health Canada

#### **MANUFACTURING ACCREDITATIONS:**

ISO 9001:2015 ISO & EN ISO 13485:2016 MDSAP ISO 14001:2015

**STORAGE:** It is recommended that gloves are properly stored away from light and extreme temperatures. Gloves should also be protected from direct exposure to ozone-generated devices such as fluorescent lights, electrical motors and x-ray devices.

Made in Malaysia





#### **THICKNESS**

#### In accordance with ASTM D3577

THICKNESS	SINGLE WALL	
Finger (at 13±3mm from fingertip)	min. 0.20 mm (7.9mil)	
Palm (at center of palm)	min. 0.15mm	
Cuff (at 25±5mm from cuff edge)	min. 0.13 mm	

#### **DIMENSIONS**

#### In accordance with ASTM D3577

GLOVE SIZE	PALM WIDTH	LENGTH
5.5	72 ± 4 mm	min. 278 mm
6.0	77 ± 5 mm	min. 280 mm
6.5	83 ± 5 mm	min. 280 mm
7.0	89 ± 5 mm	min. 283 mm
7.5	95 ± 5 mm	min. 287 mm
8.0	102 ± 6 mm	min. 288 mm
8.5	108 ± 6 mm	min. 290 mm
9.0	114 ± 6 mm	min. 290 mm

#### PRE-SHIPMENT INSPECTION

Dimension	S-2, AQL 4.0
Physical Properties	S-2, AQL 4.0
1000mL Water Leak (G-1)	AQL 0.65
Powder-Free Residue	N=6 pairs
Major Visual Inspection (G-1)	AQL 1.5
Minor Visual Inspection (G-1)	AQL 2.5

# PHYSICAL PROPERTIES In accordance with ASTM D3577

	BEFORE AGING	AFTER AGING
Tensile strength (MPa)	Min. 17	Min. 12
Ultimate elongation (%)	Min. 650	Min. 490
Modules 500% (MPa)	Max 7.0	N/A
Force at Break (N)	≥ 9	)

#### **CHEMOTHERAPY AND FENTANYL**

TESTED IN ACCORDANCE WITH ASTM D6978-05

Minimum breakthrough detection time for the following chemotherapy drugs and concentration (in minutes)

CHEMOTHERAPY DRUGS	MINIMUM TIME (IN MINUTES)
Carmustine (BCNU) 3.3mg/ml (3.300ppm)	24.0*
Cisplatin 1mg/ml (1,000ppm)	>240
Cyclophosphamide 20 mg/mL (20,000 ppm)	>240
Dacarbazine 10 mg/mL (10,000 ppm)	>240
Doxorubicin HCl 2 mg/mL (2,000 ppm)	>240
Etoposide 20 mg/mL (20,000 ppm)	>240
Fluorouracil 50 mg/mL (50,000 ppm)	>240
Ifosfamide 50 mg/mL (50,000 ppm)	>240
Methotrexate 25 mg/mL (25,000 ppm)	>240
Mitomycin C 0.5 mg/mL (500 ppm)	>240
Mitoxantrone 2 mg/mL (2,000 ppm)	>240
Paclitaxel 6 mg/mL (6,000 ppm)	>240
Thiotepa 10 mg/mL (10,000 ppm)	23.1*
Vincristine Sulfate 1 mg/mL (1,000 ppm)	>240

Caution: The testing conditions used are intended to approximate the worst case conditions for clinical use. Testing was conducted on single layer glove material. It is the users' responsibility to determine the applicability of these gloves for their intended use with chemotherapy drugs

\*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 24.0 and ThioTepa: 23.1. Do not use with Carmustine and Thiotepa.

FENTANYL RESISTANT	BREAKTHROUGH DETECTION TIME
Fentanyl Citrate Injection 100mcg/2mL	Up to 240 minutes

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