



PRODUCT SPECIFICATION

Patterson Powder-Free Chloroprene Examination Gloves

PRODUCT

Chloroprene examination glove
Non-latex
Medical grade
Non-sterile
Powder-free
Textured finish

COUNTRY OF ORIGIN

Malaysia

INTENDED USE

This is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

MATERIAL

Polychloroprene. This product does not contain proteins found in natural rubber latex.

OUTER SURFACE

Polymer coated, slightly roughened fingertips for added gripping ability.
No donning powder used

COMPONENTS

Proprietary, patented polychloroprene polymer

SHAPE

Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF

Beaded (rolled cuff)

COLOR

Aqua

SIZES

Extra small (XS), small (S), medium (M), large (L), extra-large (XL)

MARKING

Patterson Dental, 1031 Mendota Heights Road, Saint Paul, MN 55120 Tel: 800.328.5536 Fax:
651.686.0288

Packaging marked and color-coded to designated size (gloves not marked)

PACKAGING AND LABELING

Reorder Number 058-5224, 058-5463, 058-5471, 058-5489, 058-5497

200 pieces per box, 2000 pieces per case

CONTROL NUMBER (LOT NO.)

Each dispenser box and outer carton bears a production lot number

EXAMPLE: 39-220508030067

Lot number identifies production date, material batch and internal control number

QUALITY CHARACTERISTICS*

All listed standards are used in their latest edition

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
<u>Dimensions</u>		ASTM D6977
<i>Overall length</i>	240 mm avg (XS, S, M, L, XL)	
<i>Width</i>	76 mm +/- 4 mm (XS) 86 mm +/- 4 mm (S) 98 mm +/- 4 mm (M) 107 mm +/- 4 mm (L) 115 mm +/- 4 mm (XL)	ASTM D6977
<i>Thickness (single wall)</i>	<i>Finger:</i> 0.09 mm/3.5 mil avg. <i>Palm:</i> 0.07 mm/2.8 mil avg.	
<u>Physical properties</u>		ASTM D6977
<i>Tensile strength (before aging)</i>	15.9 Mpa avg.	
<i>Tensile strength (after aging)</i>	20.9 Mpa avg.	ASTM D6977
<i>Elongation (before aging)</i>	817% min.	
<i>Elongation (after aging)</i>	732% min.	

*minimum acceptable requirements of ASTM and FDA where applicable. Gloves offered by Innovative Healthcare Corp. meet or exceed these physical requirements. Independent laboratory test results are available upon request.

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

For reference purpose in accordance with ISO 2859 "Sampling Procedures for Inspection by Attributes".

All standards listed in this specification are applied to medical gloves non-sterile.

INTERNAL ATTRIBUTIVE RELEASE INSPECTION

Watertight testing, visual defects testing, dimensional testing, quantity per packing unit testing.

FINAL GLOVE RELEASE

Assurance action

ASTM D 6977 Standard Specification for Polychloroprene Examination Gloves for Medical Application

ASTM D 5151: Standard Test Method for Detection of Holes in Medical Gloves

Sampling inspection and final release information

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Pre-shipment inspection in accordance with ISO 2859, Watertight Testing, Multiple Sampling Plan, Inspection Level G1, AQL 1.5. Visual Defects, Single Sampling Plan, Inspection Level S4, Major Defects, AQL 2.5, Minor Defects AQL 4.0.

PACKAGING, MARKING, GOOD DELIVERY INSPECTION

Assurance Action

QA performs final dispenser and carton regulatory inspection. Review of pre-shipment inspection results. Final inspection of packaging integrity. Supervision of container loading.

GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with ISO 13485, ISO 9001, and US FDA 21 CFR part 820

MICROBIOLOGICAL CLEANLINESS CONTROL

The bioburdens of the finished gloves are monitored and recorded. Unusual contaminants are identified.

CAUTION: Non-sterile examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contamination.

If conditions warrant, the user may wish to minimize the risk of infection. In this case we recommend the decontamination of the gloves prior to use by disinfectants or other effective methods.

STORAGE

Store in a dry, ventilated area. Avoid direct sunlight, fluorescent lighting, heat, and moisture
Do not store above 100° F (38° C) as this will lead to accelerated aging