

DISCOVER THE VALUE BY MAKING THE BEST CHOICE

GLOVE MATERIALS: HOW TO CHOOSE THE CORRECT GLOVE

Disposable glove usage is broken down into two broad categories: Medical (including dental and veterinary) and General Purpose (non-medical). Within the Medical category, gloves can be designated (i.e., meeting all applicable standards and regulations) as Exam, Sterile Exam or Sterile Surgical.

Criteria for evaluating disposable gloves includes material composition, acceptable quality level, physical properties, and intended use. Many different agencies and organizations, define gloves and regulate their usage, including ASTM, FDA, EN, ISO, and OSHA.

Material composition can be Natural Rubber Latex or any of a number of synthetic polymers including Nitrile, Vinyl (Polyvinyl Chloride), Chloroprene, or even “blends” where more than one material is combined.

When selecting the most appropriate exam glove, it is important to consider several factors, especially material composition and physical properties.

Vinyl

Gloves made of Poly (vinyl chloride), commonly abbreviated PVC, were introduced during the 1980's and represented the first alternative to those of natural rubber latex.

Vinyl examination gloves are intended for short-term tasks and should be changed every 15 minutes or less. Appropriate uses of vinyl gloves include dispensing medication, transporting of patients, and non-invasive physical examinations.





Nitrile

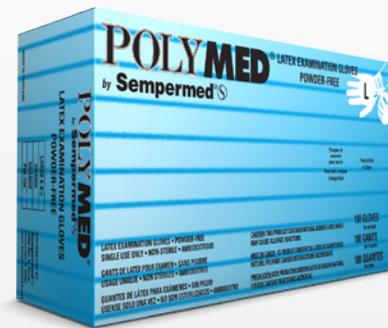
Nitrile-butadiene rubber (NBR), or Nitrile rubber, is an oil-resistant synthetic rubber produced from a copolymer of acrylonitrile and butadiene.

Nitrile examination gloves offer excellent chemical/solvent barrier protection. They are also suitable for tasks involving prolonged exposure to bodily fluids and cleaning solutions. Nitrile gloves are often the glove-of-choice when handling chemotherapy agents.

Latex

Natural rubber latex is the oldest liquid-proof glove material. It is appropriate for a multitude of uses and offers a highly elastic, comfortable fit.

Latex examination gloves are an excellent choice for general patient examinations, oral procedures, and wound care.

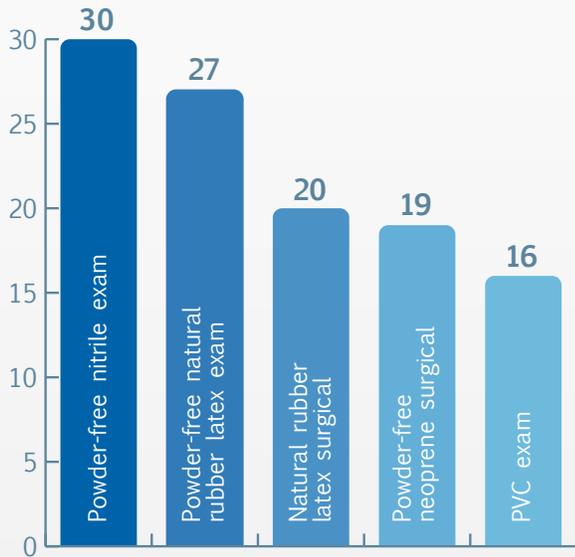


Chloroprene

Chloroprene, also known as polychloroprene or neoprene, is an elastic synthetic rubber. Chloroprene gloves are appropriate for use in nearly all procedures which require superior dexterity and tactile sensitivity. Additionally, chloroprene acts as an excellent barrier to many chemical compounds.

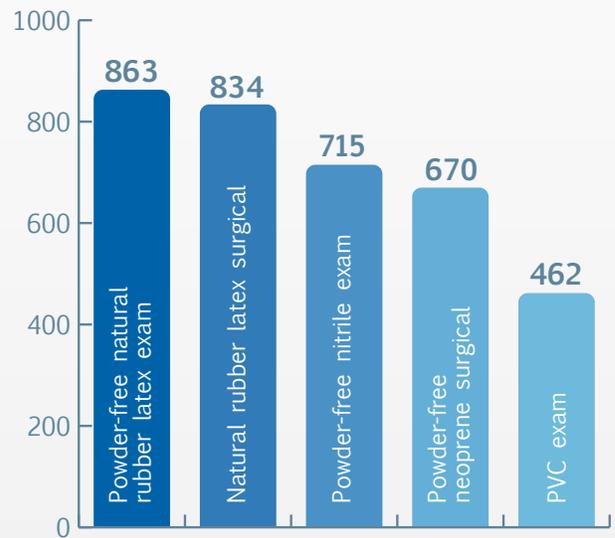
PHYSICAL PROPERTIES OF SEMPERMED GLOVES

Tensile Strength (MPa)



Tensile Strength refers to the amount of force the glove can endure before breaking. Higher tensile strength signifies a stronger glove.

Elongation (%)



Elongation refers to the amount a glove will increase or grow in length before breaking. Greater elongation indicates more elasticity.

	FDA Limit	ASTM Limit	SUSA Limit
Powder-Free Latex Exam	2.5	2.5	1.5
Powder-Free Nitrile Exam	2.5	2.5	1.5
Powder-Free Vinyl Exam	2.5	2.5	1.5
Latex Surgical	1.5	1.5	1.0
Synthetic Surgical	1.5	1.5	1.0

Barrier Protection

Acceptable quality levels (AQL) for freedom from holes refers to confidence in barrier protection. Gloves with lower AQL will have fewer barrier defects. Sempermed USA's (SUSA) internal requirements are notably more stringent than FDA and ASTM requirements.

Although gloves manufactured with different materials have comparable barrier properties when removed directly from the box and tested, it is important to realize that their actual on-the-job barrier performance varies.

Viral penetration testing

Sempermed latex, nitrile, and vinyl examination and surgical gloves have passed testing for viral penetration using the standard developed by the American Society of Testing and Materials (ASTM). This standard, F1671-97a, is entitled "Resistance of Materials Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System." Phi-X174 is one of the smallest known viruses, measuring only 0.027 micrometers in size.

Quality testing

Before each lot of gloves is released for distribution it is tested to certify their standard of quality. These tests comprise systematic actions necessary to provide confidence that a product will satisfy expected needs and requirements. These include water leak and air testing to reveal pinhole adulteration. In addition, manufacturing facilities maintain numerous management system procedures, which work to prevent contamination during all phases of the production cycle. These include guidelines for cleaning equipment, machines, and surrounding areas. The facilities also document and implement rapid corrective actions for all reported non-conformances and quality events.

Vigilance testing

Sempermed maintains a third-party testing schedule to verify dimensional and physical integrity, and regularly tests our products for resistance to viral penetration (Phi-X174 bacteriophage).

Good Manufacturing Practice

All gloves are manufactured in compliance with ISO 9001, ISO 13485, and US FDA 21 CFR part 820 ASTM D 5151: "Standard Test Method for Detection of Holes in Medical Gloves."

It is the responsibility of the glove user to establish appropriate safety protocols. This information is provided as a service of Sempermed and reflects current available information.

