CardinalHealth

Choices

Research and technology supporting your decisions

In this issue…

We'll review some common synthetic polymer films used in medical gloves and their appropriate clinical usage.

Synthetic glove materials: selection and clinical use

While natural rubber latex is the gold standard in blood-borne pathogen barrier protection, there are a number of good synthetic polymers used today in medical gloves. The key is in using the appropriate type of glove for the task.

A polymer is a material composed of molecules made up of many (poly) repeats of a simpler unit, the monomer. Another term used to describe such a molecule is macro-molecule, meaning big molecule. What all polymers have in common is that they are chemically constructed of repeats of the basic monomer unit, which is chemically bonded to others of its kind to form three-dimensional molecules, giving each polymer its unique physical qualities. The chemical nature and length of the mole-cules and their orientation in relation to each other influence the properties of the polymer and the products made from them.

Vinyl

Polyvinyl chloride (PVC) has been used for more than 50 years, since flexible (plasticized) PVC was introduced in the mid-1930s. PVC is manufactured by polymer-ization of vinyl chloride monomers.

Vinyl examination gloves are appropriate for short-term tasks involving minimal stress and risk of exposure to blood or other potentially infectious material. They are appropriate for these types of tasks as long as the barrier remains intact. You must consider the risk based on the specific procedure and the manipulations and other stresses placed on the glove film. Vinyl exam gloves may need to be changed every 15 minutes.

Nitrile

The nitrile rubbers are polymers of butadiene, acrylonitrile and carboxylic acid. Butadiene contri-butes toughness and impact resistance. Acrylonitrile contributes heat resistance and hardness.

Nitrile examination gloves are used for tasks involving prolonged exposure to blood, body fluids, chemo-therapeutic agents, cleaning solutions and other chemicals. They have high tensile strength and typi-cally better chemical resistance than natural rubber latex, especially to hydrocarbon-based solutions. They should be changed every 15 to 30 minutes for maximum barrier protection.

Neoprene

The generic term neoprene denotes rubberlike polymers and copolymers of chloroprene. Neoprenes were the first synthetic rubbers developed in the United States. Discovered in the laboratories of the University of Notre Dame and developed by E.I. du Pont de Nemours and Company, neoprene has inherent high tensile strength, elongation and wear properties.

Neoprene surgical gloves are indicated for use on all tasks and procedures requiring a sterile hand covering that accommodates fit, feel, comfort and manual dexterity. Under typical conditions, they should be changed every one to three hours depending on the type of procedure, procedure duration and level of stress placed on the glove.

Synthetic polyisoprene

The properties of synthetic polyisoprene are nearly identical to those of natural rubber. The synthetic polymers are alternatives for the natural product and are often preferred because of their greater uniformity and consistency.

Not all gloves made from synthetic polyisoprene are created equal! Cardinal Health's Esteem® synthetic surgical gloves are formulated with synthetic polyi-soprene using a unique and proprietary manufacturing technology. Esteem® polyisoprene gloves are compa-rable in tensile strength to natural rubber latex and have greater tensile strength than neoprene.

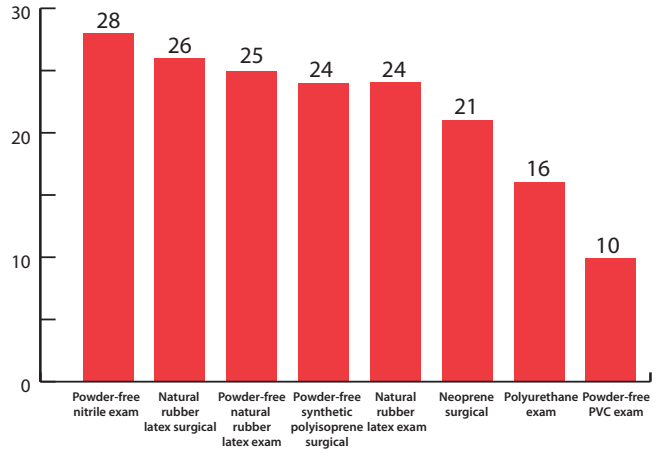
(continued)

The tensile strength of Esteem®polyisoprene exceeds the standard for both natural rubber and synthetics.

Esteem® synthetic surgical gloves are indicated for use on all tasks and procedures requiring a sterile hand covering that accommodates fit, feel, comfort and manual dexterity. Under typical conditions, they should be changed every one to three hours depending on the type of procedure, procedure duration and level of stress placed on the glove.

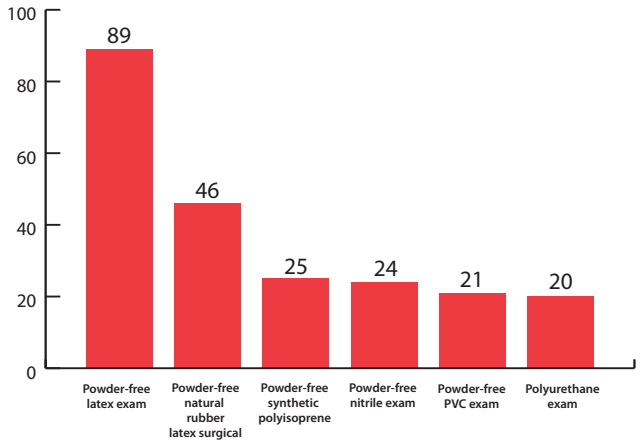
Physical properties

Tensile strength (MPa)



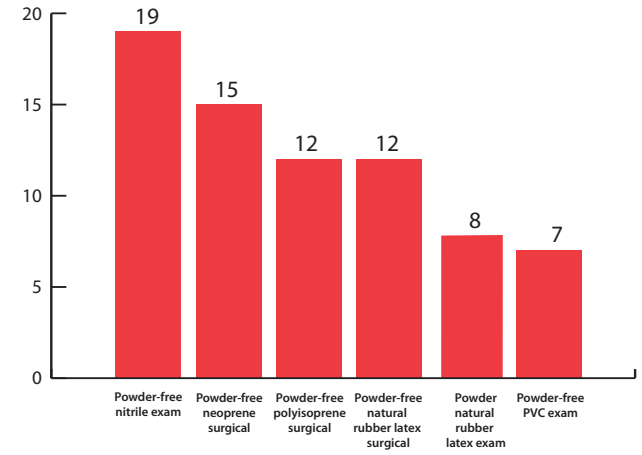
Tensile strength **relates to material strength. A higher tensile strength implies a stronger glove. The number reflects how much force is required to stretch a sample of the glove until it breaks.**

V-tear (kN/m)



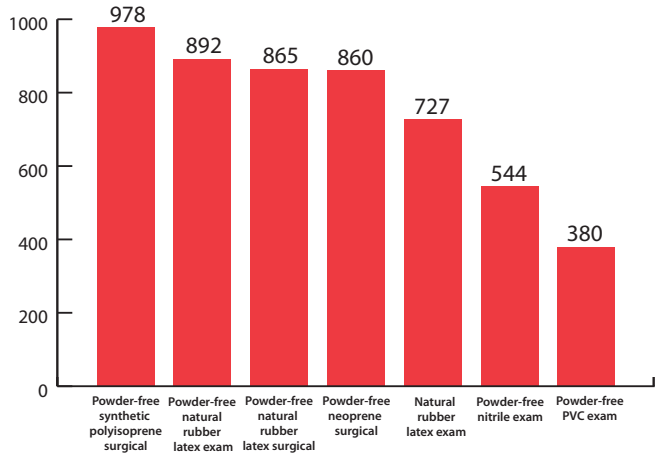
V-tear **measures the force necessary to start a tear.**

Puncture (Newtons)



Puncture **measures the force necessary to rupture the film with a stainless steel pin.**

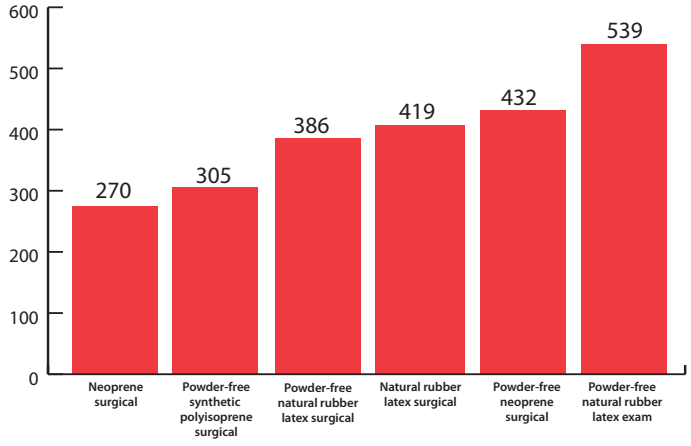
Ultimate elongation (%)



Ultimate elongation **relates to material elasticity. A higher ultimate elongation will stretch more before breaking. This number reflects how far, in percent of the original sample length, a glove stretches before it breaks. If a one inch sample stretches to eight inches before it breaks, then elongation is 700 percent.**

Comfort

Tensile stress at 500% (psi)



Tensile stress (modulus) **relates to comfort. A lower tensile stress implies a softer and typically more comfortable glove. The number reflects how much force is required to stretch the sample to a specified length. Note that the low modulus of the synthetic polyisoprene surgical glove gives it a softness and feel comparable to that of natural rubber latex.**

Barrier protection

With respect to gloves, Acceptable Quality Level (AQL) for freedom from holes refers to confidence in barrier protection. Gloves with a lower AQL will have fewer barrier defects. Our internal requirements are significantly more stringent than FDA or ASTM requirements.

Bacteriophage penetration testing

The test method used is the ASTM International F1671 "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Bloodborne Pathogens Using Phi-x174 Bacteriophage Penetration as a Test System." The method was developed to assess the effectiveness of materials used in protective clothing for protecting the wearer against contact with bloodborne pathogens. A surrogate microbe suspended in simulated body fluid under conditions of continuous contact is used. The outcome is either "pass" or "fail." Cardinal Health tests a statistically significant sample size of 32 gloves instead of the sample size of three called for in the ASTM method.

Glove selection

When choosing a glove, the first consideration should be the barrier requirement related to the procedure or task. It is recommended that you determine the level of exposure risk prior to selecting a glove.

Patient-care activities that involve exposure to blood, body fluids and other potentially infectious materials, as well as activities that may stress the glove material, such as handling of instruments and management of vascular lines, are examples of HIGH RISK situations.

Additionally, consideration should be given to contact with chemicals and disinfectants. For example, housekeeping should consider using a nitrile or utility glove.

Patient-care activities that require minimal glove use, minimal or no exposure to blood or body fluids and where gloves are used for short periods of time are considered LOW RISK for exposure. Examples of LOW RISK situations are administrating an intramuscular injection, routine suctioning, caring for a newborn, emptying a urinal and handling food.

Not all synthetic glove materials will meet the clinical barrier requirements of all patient-care tasks and procedures. Individual usage patterns and length of time that the glove is worn may also affect glove barrier effectiveness.

	FDA limit	ASTM limit	Cardinal Health limit
Powder-free latex exam	2.5	2.5	1.5
Powder-free synthetic exam (nitrile)	2.5	2.5	1.5
Powder-free synthetic exam	2.5	2.5	1.5
Synthetic surgical	1.5	1.5	1.09

All Cardinal Health gloves tested have passed the bacteriophage penetration test

Glove	Result
Esteem® powder-free synthetic surgical (2D72PL55-90)	**PASSED**
Esteem® SMT powder-free synthetic surgical (2D72PT55-90)	**PASSED**
Esteem® with Neu-Thera™ powder-free synthetic surgical (2D73TE55-90)	**PASSED**
Protegrity® and Protegrity® SMT powder-free latex surgical (2D72N0I-71 and 2D72NS55-90)	**PASSED**
Protegrity® with Neu-Thera™ (2D73TP55-90) (TSR 6232-PG)	**PASSED**
Esteem® stretchy synthetic exam (8880-8884)	**PASSED**
Esteem® stretchy nitrile exam (8810N-8814N, 8814NXX, 8815N-8819N and 8819NXX)	**PASSED**
Esteem® nitrile XP exam (N8850XP-N8854XP)	**PASSED**
Positive Touch® powder-free latex exam (8836-8839; 8840-8844; 8875-8879) and Positive Touch® XP latex exam (8860XP-8885XP)	**PASSED**

Testing conducted at Nelson Laboratories, Inc., Salt Lake City, UT. This chart features a representative sample of our gloves but is not a complete listing of gloves tested.

Gloving recommendations

Department/unit based	Synthetic polymers				Natural rubber latex
	Vinyl*	Nitrile	Neoprene	Polyisoprene	
High-risk patient-care units					
Emergency medical services	O	X	X	X	X
Trauma unit	O	X	X	X	X
Burn unit	O	X	X	X	X
Intensive care unit	O	X	X	X	X
Labor and delivery/OB		X	X	X	X
Operating rooms		X	X	X	X
Invasive radiology		X	X	X	X
Low-risk patient-care units					
Employee/occupational health services	X	X	X	X	X
Ambulatory clinics	X	X	X	X	X
Nonsurgical clinics	X	X	X	X	X
Pediatric services	X	X	X	X	X
Noninvasive radiology	X	X	X	X	X
Ophthalmology services	X	X	X	X	X
Newborn and infant services	X	X	X	X	X
Ancillary and support departments					
Food and nutrition services	X				
Housekeeping services		X			
Laboratory services	X	X	X	X	X
Reprocessing departments/CSSR		X	X	X	
Pharmacy		X	X	X	

Example task/procedures					
Food preparation and handling	X				
Cleaning, sanitation, general housekeeping		X			
Specimen handling and lab analysis		X		X	X
Direct patient care (low risk of pathogen exposure)	X			X	X
Prep and administration of chemotherapy		X	X		
Surgical procedures			X	X	X
Invasive radiology			X	X	X
Direct patient care (high-risk clinical units), e.g., ICU, ER, OR, LDPR		X	X	X	X

Remove this section for quick reference.

X = Appropriate for various procedures

*** O = Appropriate for low-risk procedures such as:**

- **Emptying an emesis basin**
- **Starting an IV**
- **Changing or emptying a urinary drainage bag**
- **Discontinuing an IV line**
- **Brief suctioning**
- **Emptying a bed pan**

A glove selection chart is also available on the Cardinal Health web site at www.cardinal.com/gloves.

In-use testing of vinyl examination gloves

We've implemented process improvements enhancing the durability of vinyl examination gloves. To gauge durability, a challenge test emulating normal examination glove use was administered by an independent testing laboratory. The experiment compared the post-challenge pinhole failure rate of vinyl examination gloves to the same rate in latex examination gloves. Each test group of gloves had a base pinhole rate of zero. Glove failures were defined as a result of glove use.

Test methodology

1. Pretested, leak-free gloves were selected randomly.

2. Each glove was labeled with a unique number for tracking.

3. A technician donned the gloves and performed the following wound-care simulation steps a total of five times. Each simulation was timed to take one minute plus or minus five seconds. The total challenge time was five minutes.

- Water was applied to a three-square-inch area on a patient's forearm.
- One self-seal pouch containing three pieces of gauze was opened.
- One piece of gauze was removed, and the water was wiped off the patient's forearm.
- The cap was twisted off a bottle containing sterile water. Another piece of gauze was soaked with the sterile water, and the wet area of the patient's arm was swabbed.
- The remaining piece of gauze was removed and placed on the patient's forearm.
- An 18-inch strip of gauze was wrapped as a bandage around the area and gauze patch.
- The cap on the sterile water bottle was replaced, and the gloves were removed carefully.
- After the fifth one minute challenge (five minutes total), each glove was water tested in accordance with ASTM 5151 "Standard Test Method for Detection of Holes in Medical Gloves." Pinhole rate failures were compared between the vinyl and latex glove groups.

Results

The failure rate of both the vinyl and latex examination gloves in this study was less than 2.5 percent *after use**. ASTM D3578 "Standard Specification for Rubber Examination Gloves" specifies a maximum failure rate of 2.5 percent for pinholes before use. The FDA also currently specifies a maximum of 2.5 percent.

**After use* is defined as the series of manipulations during the five-minute challenge as outlined in the protocol.

References and further reading

1. Korniewicz, Denise, DNSc, RN, FAAN. "Barrier Protection of Latex." *Immunology and Allergy Clinics of North America*, Volume 15, Number 1, February 1995.

2. Korniewicz, D., Kirwin, M., Cresci, K., Larson, E. "Leakage of Latex and Vinyl Exam Gloves in High and Low Risk Clinical Settings." *American Industrial Hygiene Association Journal*, Issue 64, January 1993.

3. Hamann, Curtis, MD, Kick, Shelley, PhD, Sullivan, Kim. "Taking Up the Gauntlet: Accepting the Challenge of Glove Evaluation." *Journal of Healthcare Material Management*, September 1993.

4. Association for Professionals in Infection Control and Epidemiology, Inc. *Glove Use for Healthcare Providers: Hand Covering and Barrier Protection*. 2000.

Lit. No. GLV00941 (1204/5M/MC1665)

Cardinal Health
Glove Products
1500 Waukegan Road
McGaw Park, IL 60085

www.cardinal.com/gloves

CardinalHealth