CardinalHealth

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In this issue…

We analyze advances in powder-free glove coatings and highlight nitrile, the newest coating with many benefits.

Polymer coatings for powder-free medical gloves

New technologies provide alternatives

Several coating technologies have been developed to reduce the amount of powder or to replace powder used in the manufacturing of medical gloves. Historically, powder has been used to facilitate the release of gloves from formers during glove forming and to aid in glove donning. However, polymer coatings in combination with chemical lubricants are often applied to the glove surface to provide optimum wet and dry donning capabilities.

A majority of the coated surgical gloves on the market are manufactured by applying polymer coatings to the inner glove surface. This is followed by postforming processes such as chlorination and lubrication. The chlorination process oxidizes the outer rubber surface to reduce the surface tackiness and also removes most of the powders deposited on the outer glove surfaces.

Key requirements for polymer coatings

Polymer coatings appropriate for medical gloves must have certain key characteristics. To provide a high-quality glove on a consistent basis, it is critical that a polymer coating is designed and engineered to meet all of these requirements.

- It must adhere to the underlying rubber latex substrate and offer durability and good donning characteristics.
- It must be resistant to chlorination and the vigorous postforming processing steps that include rinsing, extraction and drying.
- It should not degrade after sterilization.

Types of coatings

Synthetic polymeric coatings for medical gloves are generally made from hydrogel, acrylic, polyurethane, silicone polymers or polymer blends. The type of polymer used depends on the intended use of the device, device material and other processing requirements. The following coatings have been used on medical gloves for years. Each of the technologies has benefits, yet each also has some significant drawbacks.

Hydrogels

Introduced to the medical device industry in the early 1960s (Wichterle & Lim, 1960), hydrogel coatings represent rather antiquated technology. Hydrogel coatings do not dissolve in water and exhibit the ability to swell and absorb a significant amount of water – as much as 20% of their weight (Ratner & Hoffman, 1976). Hydrogel coatings are used on medical products, such as catheters, angioplasty balloons, introducers, contact lenses and other indwelling medical devices, to enhance surface lubricity (Ikada & Uyama, 1993). In these applications, the absorbed water in the hydrogel coating forms a thin water film on the contacting surface. This allows for device movement.

Because of the vast difference in elasticity between natural or synthetic rubber and the hydrogel coating, the coating tends to crack while forming, stripping gloves from the former or donning. If the adhesion of the coating to the rubber is poor, the coating flakes off from the substrate. These coating flakes could generate particulate matter. Therefore, it is critical for the hydrogel coating to adhere well to the underlying

(continued on next page)

rubber substrate, providing integrity during donning. Surface treatment processes have been developed to circumvent the potential coating adhesion problem, including treating the rubber layer with acid solutions or with a polymeric adhesion "tie layer" before applying the hydrogel coating. The treatment can be effective, but it is critical that the process is under control. In terms of physical properties, tensile strength and puncture resistance are typically low in hydrogel coatings.

Polyurethanes

Polyurethane materials are used in a variety of blood-, tissue- and skin-contacting medical devices due to their excellent biocompatibility and wide range of material properties. Polyurethane materials can be very hard and rigid, such as those used for the adhesives for hemodialysis cartridges, or very soft and elastic, such as those used for catheters and medical tubings. Polyurethanes are hydrophilic in nature, meaning that they tend to absorb water. The degree of water absorption is dictated by the chemical constituents used in the synthesis of the polymers and by the structure of the polymer. As a result, polyurethanes become softer and sometimes exhibit slight surface tackiness after exposure to water. Polyurethane coatings used in medical gloves are generally applied directly to the latex substrate using water-based polyurethane dispersions. Some polyurethane coatings are not suitable for medical gloves because the surface becomes too tacky after the gloves are chlorinated.

Acrylics

Acrylic coatings are based on acrylate polymers that have elastic properties. Although the acrylate polymers can be rendered rubberlike by copolymerization with different monomers, their tensile strength and elongation are relatively low compared to those of natural rubber. Because of this mismatch in mechanical properties, acrylic coatings applied to rubber gloves typically crack and sometimes delaminate (separate from the substrate). In addition, these polymers are sensitive to certain chemicals often used in the off-line processing of powder-free gloves (Strassburg, 1988).

Silicones

Silicone coatings are used primarily to improve the surface lubricity of medical devices. As surface coatings, they can be used alone or blended with other types of polymers. Silicones are applied by either a solvent- or water-based system. Silicones that migrate to the surface of the medical device are best for enhancing lubricity. These types of silicones are leachable and can be transferred to any object they contact. Leachable silicones can leave an oily feel on skin after gloves are donned. In addition, they do not provide adequate damp and wet donning characteristics.

Nitrile: A new coating with outstanding benefits

Nitrile generally is referred to as a synthetic polymer that is composed of three monomers: acrylonitrile, butadiene and carboxylic acid. Acrylonitrile monomer provides material hardness and permeation resistance to a wide variety of chemicals and solvents, especially to hydrocarbon oils, fats and solvents. After vulcanization, butadiene offers softness and flexibility, and carboxylic acid provides high tensile strength and tear resistance. Because of these unique properties, nitrile gloves are used widely in laboratory environments where chemicals are handled and in critical environments such as electronics manufacturing. Due to the excellent barrier properties and superior puncture and tear resistance, nitrile recently has become a popular choice for synthetic medical gloves.

Although nitrile has been widely used as a laminating material for industrial gloves, until recently, it has not been used as a powder-free coating for medical gloves. Nitrile coating, however, offers the following benefits as compared to other polymer glove coatings such as hydrogel and polyurethane:

- Good tensile strength and elasticity
- Increased lubricity after chlorination
- Good adhesion to natural rubber and excellent chemical resistance

Key characteristics of various types of polymer coatings are summarized in the following table (Billmeyer, 1984; Pauly, 1989).

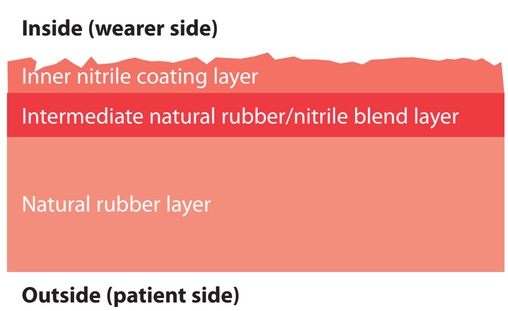
Key characteristics of various polymer coatings

	Coating Type				
	Hydrogel	**Polyurethane**	**Acrylic**	**Silicone**	**Nitrile**
Tensile strength	Low	Medium-High	Low	Low	High
Adhesion to natural rubber	Low	Medium	Medium	Low	Medium
Elongation	Low	High	Low	Medium	High
Lubricity after chlorination	High	Medium	Medium	High	High
Puncture resistance	Low	Medium-High	Medium	Low	High
Abrasion resistance	Low	Medium	Medium	Low	Medium
Oil resistance	Medium	High	High	Low	High
Hydration/water swelling (lower is better)	High	Medium	Low	Low	Low
Integrity after stretching	Low	Medium-High	Low	Low	High

The anatomy of the Protegrity® powder-free glove

Cardinal Health Applied Technology Center and Gloves Research and Development groups have developed a TRI-layer Polymer LatEx Dipping (TRIPLED℠) technology to produce an innovative powder-free nitrile-coated surgical glove. The Protegrity® nitrile-coated glove consists of three strongly adhered, inseparable elastomeric layers which are cross-linked, or vulcanized, during the manufacturing process. Vulcanization is a chemical process that gives rubberlike characteristics to polymers.

Schematic of a trilayer polymeric structure fabricated using TRIPLED℠ technology



Natural rubber latex outer layer

The outer layer is a vulcanized natural rubber based on our proprietary natural rubber latex formulation. This layer provides desired glove properties, such as a soft feel, high tensile strength and elasticity.

Intermediate blended layer

The intermediate layer consists of a blend of nitrile and natural rubber specially formulated to enhance the adhesion of the inner nitrile coating to the natural rubber substrate. The intermediate rubber blend layer also provides a surface hardening effect and unique surface micro-texture morphology to enhance glove donning characteristics. These features increase material stiffness near the surface and minimize stickiness between the inner glove surfaces to improve donnability.

Inner nitrile coating

The inner layer is a powder-free nitrile synthetic coating formulation designed to provide the ideal surface characteristics for glove donning.

The inner nitrile coating on the Protegrity® glove is relatively thin and extremely durable, as evidenced by coating surfaces. Stretching up to 300% of its original length does not have a significant effect on the integrity of the coating (see Figures 1a–1c). The coating appears to adhere strongly to the underlying substrate. This multilayer film formation approach allows us to design a surgical glove with unparalleled strength and barrier protection and an optimized surface for donning.

The Protegrity® glove is formed on our custom surgical glove formers. The custom glove formers were designed using advanced engineering prototyping to provide the ideal fit for most hands. To further enhance glove donnability on wet and damp skins, these coated gloves are processed off-line using our proprietary surface modification technology. The glove is then sterilized by our Ster-E-Beam℠ electron beam process. The entire process produces a sterile powder-free glove with superior fit, soft feel, excellent gripping properties and outstanding donning.

Summary

New and technologically advanced coatings, such as nitrile, allow glove manufacturers to produce powder-free surgical gloves with the same excellent donnability, durability and tactile sensitivity users have come to expect from powdered gloves. We selected nitrile for the Protegrity® surgical glove coating because of its excellent barrier properties, impressive tensile strength, superior puncture and tear resistance, and exemplary donning properties.

Our proprietary manufacturing technology creates excellent adhesion between natural rubber latex and nitrile, resulting in an innovative surgical glove that provides consistent protection and performance for health-care workers and patients.

References

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Scanning electron micrographs (SEMs) of glove coatings

The following SEMs represent the surface morphology of a typical glove sample magnified 1000X. Each sample was stretched 0%, 100% and 300%. The nitrile coating of the Protegrity® glove does not crack even when stretched to 300%. The hydrogel and polymeric coatings both display cracking.

Protegrity® glove with nitrile coating

Figure 1a. Stretched 0%

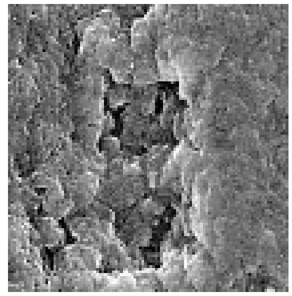

Figure 1b. Stretched 100%

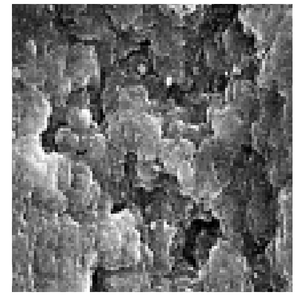

Figure 1c. Stretched 300%

Surgical glove with hydrogel coating (note cracks in coating)

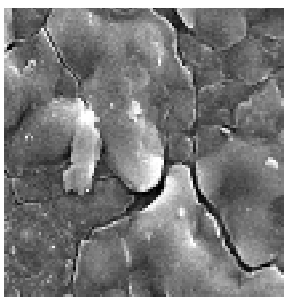

Figure 2a. Stretched 0%

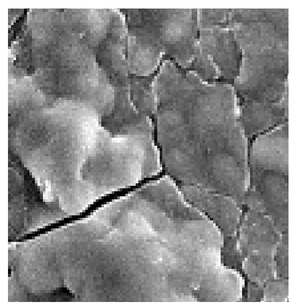

Figure 2b. Stretched 100%

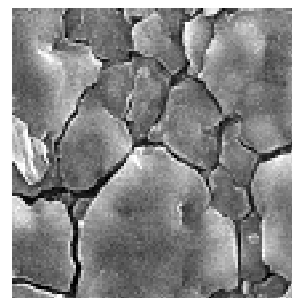

Figure 2c. Stretched 300%

Surgical glove with polymeric coating (note cracks in coating)

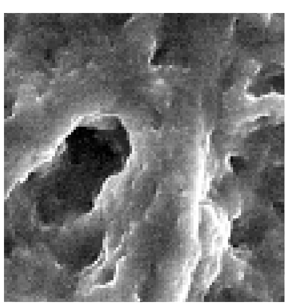

Figure 3a. Stretched 0%

Figure 3b. Stretched 100%

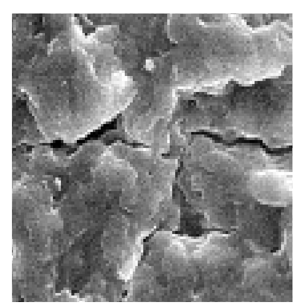

Figure 3c. Stretched 300%

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