

2008 Glove Buyer's Guide



Weighing glove options: A balance of safety, comfort and costs

by Jeannie Akridge

There are a lot of factors that go into making a smart glove selection. Key features to consider in any glove evaluation include, but are not limited to: barrier protection, comfort, fit, feel, tactile sensitivity, elasticity, modulus, donnability, durability, tensile strength, puncture resistance, chemical resistance, texture, allergenicity, cost-effectiveness and even standardization issues.

“The most important factor is selecting the glove that provides the level of protection required for the task at hand,” said Keith Kuchta, general manager, medical supplies, [Kimberly-Clark Health Care](#), Roswell, GA.

Peter Sewell, director of product development, [Tronex Company](#), Parsippany, NJ, advised, “Check that the glove provides the correct type of barrier protection against the exposure risk level involved against contaminants, drugs, infection, body fluids, chemicals or providing protection to a patient. Ensure the glove is right for the task being performed and the duration the glove is being worn.”

Milt Hinsch, technical services director, [Mölnlycke Health Care](#) (maker of Biogel Surgical Gloves), Norcross, GA, also advises buyers to look for a low Acceptance Quality Level (AQL) for holes according to both the FDA standard and the more rigid ASTM AQL standard of 1.5 for surgical gloves. “The glove can be absolutely perfect in every other way, but if it has a hole in it, nothing else really matters.” (The AQL for Mölnlycke’s surgical gloves is 0.65).

Allergy issues, in particular those associated with natural rubber latex gloves, are receiving a great deal of attention with institutions like Johns Hopkins School of Medicine making much publicized moves away from latex in gloves and other products¹. You too may be wondering whether latex should be eliminated from your facility.



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While it's something that every facility will have to answer for itself, in general glove manufacturers, group purchasing organizations and professional organizations agree that, although the goal needs to be latex-free for individuals with a latex allergy, pursuing a "latex-safe" environment may be a more realistic approach overall.

For one, "it's almost impossible to go completely latex-free in a facility," said Amy Herrin, portfolio executive at group purchasing organization Novation, Irving, TX. "We've tried to aid in providing messaging to our members that focuses on being latex-safe versus being latex-free."

"We still think that latex-safe is usually the best way to go," agreed Hinsch. "Even though there are some hospitals that want to go latex-free – we'll help them if they want to do that—we often advise them that might not be the best way to go and discuss the benefits of latex-safe and latex-free with them. There are situations where latex-free can be beneficial – such as in children's hospitals – and other situations where the cost of going latex-free might outweigh the benefits."

Nor is it easily feasible to go completely latex-free. "There are over 10,000 medical items that have latex in them," Hinsch continued. "You would have to change every single one of them to latex-free to truly claim that a facility is latex-free."

Identifying latex-free alternatives is a chore at best. "One of the challenges for hospitals is finding out which products are latex-free," said Gina Pugliese, RN, MS, vice president, [Safety Institute, Premier Inc.](#), Charlotte, NC. She noted that while there is a labeling requirement for products that contain latex, there is no such requirement for manufacturers to label products as being latex-free. To help guide member facilities in their quest to provide safe products for latex-allergic employees, physicians and patients to use, Premier recently introduced a 600-page latex-free catalog that identifies 16,675 latex-free items in 250 product groups representing 445 suppliers.

[Novation](#) also provides a resource for its members who are tasked with selecting products for a latex-safe environment, but with a slightly different approach. "We have a database of products that contain latex," said Stephanie Hale, RN, MBA, MHA, senior clinical manager – safety of contract and program services at Novation. "If you look at the database it shows you that we only have this many contracts with latex in them, period, the rest of the contracts do not." Hale added, "In updating the database, a lot of the contracts came off – either companies went latex-free, or specific products went latex-free. I was very pleased with that."



[Council](#), Washington, DC, commented, “The recent news report on the availability of a catalog of latex-free hospital products meant for employees, patients and physicians with latex allergies made by Premier will be very helpful for these allergic individuals to enable them to select the right products for their safe use. On the other hand, a whole-sale discrimination against latex gloves in hospitals should be cautioned. Such a move would not only often incur much higher healthcare cost (more than necessary), and depending on the type of gloves chosen, it could also expose users and patients to health hazards that may be more serious than the latex allergy fear. Gloves that appear to have more latex-like characteristics are usually the most costly ones. On the other hand, the use of the less expensive ones could compromise the health safety of healthcare personnel and their patients due to the glove’s inferior barrier performance, among other health hazards, such as vinyl.”

Herrin agreed that an indiscriminate ban on latex is not the answer. “We’ve tried to temper the panic if you will of ‘I’ve got to go latex-free all at once’. Not necessarily. It’s just determining if that’s an appropriate move across your facility and carefully planning the transition.”

Certainly there are benefits to natural rubber latex (NRL). “Natural rubber latex can’t be beat when it comes to barrier properties, modulus (comfort and feel, that it conforms to the hand the way the hand is meant to curve), also in tactile sensitivity,” said Bill Doyle, president, [Vystar Corporation](#), Atlanta, GA. The company produces Vytex Natural Rubber Latex for use in gloves, catheters and condoms, for example. Not to be overlooked is the additional cost of moving to a latex-free environment.

Herrin noted that Johns Hopkins is now using neoprene and polyisoprene synthetic gloves in its operating rooms. “One of the things they speak to directly is that neoprene and polyisoprene is going to cost 50 percent more than a latex glove, so how do you measure that , how do you handle that? It’s important to quantify the long-term value of moving to synthetic products, and that value can be measured in more than one way.”

Latex-safe environments

Reactions to latex can range from localized skin irritation to life-threatening anaphylaxis.

Jeffrey Martin, CEO and president of Maricopa, AZ-based [Yulex Corporation](#) which produces Yulex natural rubber latex made from guayule, explained, “Type I latex allergy is an immediate response. It’s systemic in nature and can lead to anything from itching, irritation, red eyes, wheezing, to anaphylaxis and death. It’s associated with the proteins in the latex. And type IV is more of a delayed response; it is more localized in nature than systemic. It’s generally an allergy to the chemicals that are used in the manufacturing process to produce gloves.”

Latex allergy is a “dose-related phenomena” added Martin. “The more protein you’re exposed to, in not only a single exposure, but over time, the more it increases your probability for sensitization. So it’s our aim to have the lowest amount of protein available considering when you’re using natural materials, by nature, by definition, they’re going to contain some protein.”

“The second issue is the type of protein,” he said. “People have developed an immunological response (antibodies) to specific proteins in Hevea latex. It’s been proven by clinical studies, some conducted at Johns Hopkins, that people who have developed an immune response to antigenic proteins in Hevea don’t recognize the proteins in guayule, and there’s no cross reaction. So even people who are severely allergic to Hevea latex can safely use guayule latex without the fear of an allergic reaction,” said Martin.

An entirely different botanical source than traditional Hevea latex, Yulex’s medical grade guayule latex comes from a dessert shrub grown in Arizona, versus a tropical tree in Southeast Asia. “We have been

working with some of the leading surgical/medical glove, condom, and catheter manufacturers and marketers in the U.S., Europe and Japan, and we have now demonstrated that we can successfully manufacture all of these products to the industry standards. These products are more than acceptable to surgeons, nurses and consumers who would purchase them,” said Martin. “We will be looking for the first FDA approvals for very specific products that are in the pipeline. We hope to be able to come to market very shortly with announcements on guayule latex products.” He noted that Yulex meets ASTM D1076 06, the highest standard for a medical grade latex.²

Hinsch noted that all of Mölnlycke’s latex gloves are low protein and tested for pyrogens. “The Lowry test is required by the FDA to support the less than 50 microgram/gram claim for low protein. We go one step further and perform an ELISA test, which is a test for the antigens or potential allergens and try to maintain levels below detectable limits. ”

Vystar’s Doyle explained, “Low protein means that from a total protein content that the product is below 50 parts per million. But truly the main glove companies have really strived to take a look at this antigenic level. In order to test below detection on antigenic levels you have got to be less than 0.2 micrograms per gram.” Vytex NRL is natural rubber latex in which the antigenic proteins are deactivated without affecting the desirable properties of latex. According to Doyle, over 100 different companies have expressed strong interest in Vytex NRL. “We have already completed our first production run that’s been completely allocated for samples into various industries. We have manufacturers of surgical gloves, exam gloves, condoms, breather bags, tubing, male external catheters, foam, threads, and adhesives. The biggest market is gloves, no doubt.” He speculated that a glove made from Vytex NRL could be on the market by the end of the year. “We should start the 510(k) process with a particular manufacturer as early as the second week in March.”



Gloves made from Vytex Natural Rubber Latex

Powdered latex gloves provide an especially unique challenge as latex proteins can bind to the powder and become airborne. Pugliese noted, “We’re seeing 80 percent of glove purchases being non-powdered.” The problem with powdered gloves, she explained, is that “the powder in the gloves aerosolizes and suspends the latex particles into the air and then you inhale them. So individuals in the area where latex gloves are being used may be exposed to latex particles through inhalation without ever coming in direct contact with latex or wearing latex gloves. ”

“The surgeon may not be allergic to the latex but the patient may certainly be,” added Hale. “Powder should not be in the OR in my perspective.”

Emphasized Hinsch: “There’s a good reason to go powder-free because going powder-free is so easy to do, and it is recommended by every major medical organization in this country. Surgical glove donning powder permits easy glove donning but can cause unwanted problems for wearers and surgical patients. Surgical

gloves today do not require donning powder for easy, damp-hand donning.”

Dr. Yip noted, “Latex protein allergy arose in the healthcare settings due to repeated exposure of high levels of latex protein allergens to certain sensitive individuals. This is particularly the case with the older generation of latex gloves which had no control over the residual protein and powder contents, and were used frequently in the late 1980s and 1990s. Much effort has since been made by the latex glove industry in Malaysia to address this problem. Advancement in latex glove manufacturing has now led to the production of low-protein latex gloves via reducing the protein content of either the starting latex or the gloves during the processing.”

She added, “A number of recent independent hospital studies in the U.S., Canada and Europe have demonstrated that the use of the low-protein gloves (particularly powder-free) vastly reduces the incidences of latex protein sensitization and allergic reactions in the workplace. More importantly, latex allergic individuals wearing non-latex gloves can now work alongside their colleagues donning these improved latex gloves, and suffer no ill effects. One study even showed that latex sensitive workers could also wear the improved latex gloves, but it is recommended that latex allergic individuals should opt for non-latex gloves.”

“To help glove users identify gloves with low-protein and to be assured of the quality of the gloves they use, Malaysia, the largest medical glove supplier in the U.S. (for both latex and synthetic), has introduced a quality certification program – the SMG or the Standard Malaysian Glove. This program, developed in consultation with the FDA and other relevant authorities, ensures the manufacture of quality low-protein gloves which are either powder-free or lightly powdered. All SMG-certified gloves have to meet very stringent technical requirements, such as high barrier and other physical properties, in addition to low upper limits of proteins and powder.”

According to Scott Goldstein, product manager, Surgical Gloves Division at [Medline Industries Inc.](#), Mundelein, IL, “Medline’s low-protein powder-free latex surgical gloves are extensively washed to leach out as many lingering latex proteins as possible, significantly lowering the latex protein content allowing you to use the safest possible latex.”

[Ansell Healthcare](#)’s powder-free latex surgical gloves are also low in protein content, and contain 50 µg or less of water extractable protein per gram.

So how do hospitals achieve a latex-safe environment for their healthcare workers, physicians, and patients? “By using low allergen, powder-free latex gloves for people who are not known or suspected to be latex sensitized, using non-latex gloves for the healthcare workers who are sensitized, and of course making sure everyone touching a sensitized patient must wear latex-free gloves. Other medical devices – catheters, bandages, adhesives, tubing, syringes, tourniquets, etc. also must be latex-free,” summarized Hinsch.



Cardinal's Esteem NV synthetic Powder-free exam glove

According to Diane Sosovec, RN, MS, director, clinical marketing, [Cardinal Health](#), McGaw Park, IL, “To meet the needs of latex-allergic and latex-sensitive individuals, we encourage healthcare facilities to follow the latest guidelines from the Association of periOperative Registered Nurses (AORN) that call for avoidance of natural rubber latex (NRL) products. While Cardinal Health manufactures NRL Powder-Free surgical gloves (Protegrity) with the lowest levels of latex protein available on the market, we recommend synthetic products for anyone wanting to go latex-free.”

Determining who in the facility is at risk for latex allergies through a complete history, questionnaires, or other screening methods such as allergy testing should be part of every latex-safe initiative. “If you’re not totally latex-free, you still need to have a way to evaluate the potential latex allergies among your patients and staff,” said Pugliese. “That has to be part of the history for a patient, collecting information on that so you know.”

She pointed to a recently released Safety Bulletin from the Occupational Safety and Health Administration (OSHA)³, that states, “Laboratory and clinical evidence indicates that an association exists between allergy to some natural rubber proteins and allergy to some proteins in certain foods and plants (e.g., avocado, banana, kiwi, chestnut) and some aeroallergens (e.g., pollens, grasses). A history of multiple surgeries has also been reported to be a risk factor for NRL allergy.”

Advised Pugliese, “There are different levels I think of achieving latex-safe. It can be by procedure tray, it can be a procedure room, it can be a wing of the hospital. If you have a lot of children for example who have spina bifida, which is a very high risk for latex allergies because of their multiple exposures to latex through all of their multiple surgeries, you may create a whole wing of the hospital that’s latex-free or latex-safe. You may have a latex-free crash cart for resuscitation. You may have a latex-free operating room. So some hospitals have focused on creating latex-safe environments in high risk areas and others have found it easier as a goal to go to a latex-free hospital.”

Hale suggested that it would probably take no more than a surgeon seeing one patient experience a severe allergic reaction to latex to convince them to accept safer substitutes. She recounted a recent phone call from a surgical nurse who was working with a child who was documented as having an allergy to latex, yet was still anesthetized with a latex mask. “The reaction was so severe, she didn’t want to work another case after that,” said Hale. “The patient had to be intubated for a longer time post –op. It was a fire drill during the procedure to even get the patient stabilized. So it’s just not worth it. I know that cost is always a concern, but just one death or one severe reaction is one too many from a safety perspective from my point of view.”

Synthetic options

Synthetic materials used in today’s gloves are coming closer and closer to mimicking the desirable qualities of natural rubber latex (NRL). For example, “Polyisoprene is the newest Mölnlycke surgical glove material and it mimics the feel of NRL more closely than [older generation] polychloroprene because it is made of the same polyisoprene building block that forms NRL,” said Hinsch.

Latex-free surgical glove use has grown by about 20 percent per year from 2005-2007, noted Sosovec. "There are more than 100 hospitals that have chosen to totally convert to latex-free with Cardinal Health's Esteem Polyisoprene Powder Free surgical gloves." Cardinal Health's Esteem Powder-Free exam gloves are available in nitrile, vinyl and a proprietary nitrile/vinyl blend.

She added, "The exam glove market continues to expand by 6 percent year over year and is projected to exceed 13 billion units. A key driver of this growth is in the powder-free Nitrile and Vinyl glove category."

"We have seen at least a 20 percent growth in the nitrile market every year for the past few years," said Kuchta. Kimberly-Clark has had success in moving facilities house-wide to its STERLING Nitrile exam glove. "Our Sterling Nitrile exam glove is designed for users who need a latex-free solution without having to compromise the performance, comfort and tactile sensitivity that has historically been associated with latex gloves. Sterling is made using a new process that allows Kimberly-Clark more control over the manufacturing process, which, in turn, gives Sterling consistent formation throughout the glove. Our proprietary compounding process also gives Sterling a higher level of strength than other Nitrile Gloves." (For more information on nitrile conversions, see "[Infection Protection](#)").

[Sempermed](#) (Clearwater, FL) recently reintroduced its SemperCare nitrile powder-free exam glove. SemperCare Nitrile is now manufactured as a co-polymer glove to provide an even better fit and feel. This non-latex alternative uses a manufacturing process called "fusion" bonding which creates a multi-layered glove that adds the comfort and elasticity of latex with the safety of nitrile.

"Medline's Sencicare surgical gloves are made of Isolex, a proprietary synthetic Polyisoprene," said Goldstein. "This material is nearly identical to latex on a molecular level. Because of this, Medline can offer the fit, feel, comfort, and performance of traditional natural rubber latex gloves, but without the harmful proteins that can cause allergic reactions including anaphylactic responses. For facilities struggling to make the switch to latex-free surgical gloves, Medline offers a synthetic second generation Neoprene surgical glove. The Neolon 2G has properties similar to latex, making it a tremendous value."

[Ansell Healthcare](#) (Red Bank, NJ) provides two excellent non-latex surgical glove options - the Derma Prene Ultra surgical glove made of neoprene and the new Derma Prene IsoTouch polyisoprene surgical glove. The Derma Prene Ultra provides the additional benefit of being accelerator-free; the manufacturing process does not use chemicals known to contribute to Type IV allergies. Ansell also offers non-latex exam gloves made from nitrile, neoprene and stretch vinyl.

*Yulex natural rubber latex
is harvested from
Guayule shrubs*

"With the heightened awareness of latex-allergy issues, many types of medical gloves are available to the end user. Each of them offers unique advantages, but at the same time, each of them comes with properties unique to the gloving materials. No single

glove provides the 'perfect' solution for all applications, and it is nearly impossible for a hospital to standardize on a single type of glove material without encountering difficulties. Education about gloving material and all of the aspects of the glove assures you make an informed decision when choosing the right glove for the right task," said Pam Werner, RN, Ansell clinical consultant.

Sewell noted, "Tronex synthetic gloves come in a range of different styles and properties, with the benefit of being latex-free and less expensive than nitrile and latex. Our special stretch Vinyl compounding provides excellent elasticity and tactility to reduce hand fatigue. The glove range covers powdered and powder-free, and Tronex also has a vitamin E glove to help protect people with sensitive skin. Good training, internal procedures and working knowledge of the task being performed and associated risks in a

work area are key in the end users' selection of the right gloves," he added. "Tronex has a Safety through Education program with the tools and information to help the end user with glove selection."

Price concerns

With price always a concern, how can facilities cost-effectively manage a change to a latex-safe glove program?

Herrin recommends facilities work closely with suppliers to help drive standardization and cost savings. "The key is the level of collaboration between materials management and surgical services," said Herrin of a successful surgical glove conversion. "If there's really good linkage there and both the clinical and financial questions can be answered in tandem, you can achieve some standardization. And the good news is that our suppliers keep expanding their product line, so one supplier can meet a lot of different needs now."

Standardization to one brand of gloves is possible with the right supplier, but standardizing on a single surgical glove is highly unlikely. "What we sometimes hear from customers is they want to standardize to one surgical glove," said Hinsch. "It's not realistic. There is too much variation in demand by the surgeons who have a lot of power and they have realistic needs." Orthopedic surgeons need a different glove than an eye surgeon, for example.

"Mölnlycke works closely with customers to help them manage their surgical glove needs – including minimizing the number of surgical glove brands used in the facility. Usually, Biogel gloves replace many other brands with only a few Biogel brands. While we can't standardize customers to one glove, we can standardize them to one brand, and we help many customers save a lot of money by doing that."

Rick Wright, assistant vice president, sales, Tronex, offered, "The opportunity for standardization can come from a number of areas; within the healthcare facility certain functions can be covered by a standard type of glove product, such as in a pharmaceutical environment standardized gloves are chemo-rated. Tronex exam gloves and their properties have been carefully selected to cover a range of usages that other manufactures are unable to cover without a much larger range of gloves."

"Vendor standardization can be achieved by partnering with a healthcare company such as Cardinal Health that provides the broadest product offerings in both surgical and exam gloves," said Sosovec.

Novation's clinical resource guide for exam and surgeon's gloves gives members best practices or processes to follow, links to educational programs offered by suppliers, as well as a snapshot showing the pros and cons of different glove materials. To help with conversion issues and tier maximization, Novation also offers its online CVA contract value assessor tool, a web resource portal where members can upload their current surgeon glove spend, and receive product cross-referencing information as well as a customized conversion summary.

Herrin emphasized, "Work with your suppliers. Tap into what it is that they've got available. Don't be afraid to lean on them and press them and find out what kind of support they can bring in to help you, what sort of data they have available. Leverage them as more than the guy who's coming in to sell me my box of product. These suppliers have a lot of resources at their disposal and put a lot of work behind their product line so I always encourage members to tap into that and use it to their advantage."

"Ansell Healthcare has had its finger on the pulse of glove evaluations for nearly 100 years. Through our 10-step evaluation process, we have helped hospitals of all sizes make a smooth transition from powder to powder-free and from latex to non-latex, as well as consolidating from multiple suppliers to one, said Lori Jensen, RN, Ansell Clinical Consultant. "We also understand that you must accommodate a number of internal constituencies, and we work with each to ensure their ultimate satisfaction."

To learn more about the 10-step process and find out how Ansell can help you conduct a highly successful glove evaluation, visit: <http://www.ansellhealthcare.com/Products/GloveEvaluation/10Step.aspx>.

According to Goldstein, Medline's dedicated sales representatives, O.R. Specialists, and clinical nurses will work with the facility prior to, during, and after the surgical glove evaluation and determine the best possible product mix. "We work with the facility to accomplish goals such as SKU reduction and can offer cost savings as well."

Pugliese emphasized, "You can't make a decision for the organization to become latex-free without having a multidisciplinary group to consider all the options. And there are a lot of components to being latex-free. Many hospitals find it helpful to conduct a pilot in one or two units and use the feedback to improve. Some hospitals find it easier to create latex-safe environments in high-risk areas than to go totally latex-free, and other hospitals find it easier to go latex-free."

Many clinicians and other experts stress that the move to a latex-free environment may just pay for itself in avoidance costs. Kuchta related, "Latex reactions can be expensive for a hospital. From a financial perspective, the impact to a facility of having a latex allergy case can range from employee job reassignment and training to employee workers compensation, and, in extreme cases, litigation."

"The cost can be a burden to facilities, but the cost of just one case of anaphylactic shock caused by latex in either a patient or a staff member can financially justify the conversion to latex-free surgical gloves," said Goldstein.

A reduction in employee and patient treatment costs, time off work, workers compensation costs and the like may quickly offset the added cost of moving to synthetic and powder-free gloves. "You can actually have a decrease in your overall bottom line if you look at those types of issues," said Hale. "It's just a cost they'll have to consider, an overall cost for safety."

References:

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3. U. S. Department of Labor, Occupational Safety and Health Administration, Safety and Health Information Bulletin, SHIB 01-28-2008, "Potential for Sensitization and Possible Allergic Reaction To Natural Rubber Latex Gloves and other Natural Rubber Products" <http://www.osha.gov/dts/shib/shib012808.html>
4. GHX/ HPIS Data, 2007 Domestic Data

Antimicrobial Hand Hygiene Products

Chart of Vendors

