HEALTHCARE PURCHASING NEWS
Industry leader for over 30 years

People, Places, Processes & Products that Influence the Supply Chain

## INSIDE THE CURRENT ISSUE

February 2009

**Infection Connection**

### The right glove for the right job at the right price

# Keeping gloves on hand

*by Jeannie Akridge*

**H**ospitals may be breathing a small, albeit possibly temporary, sigh of relief as cost increases for medical gloves seem to have slowed.

"After a very volatile year in 2008, the market has already begun to stabilize," commented Poyee Tai, executive vice president, Tronex Industries. "In October 2008, declines in raw materials and freight costs should contribute to a decrease in the cost of gloves by the end of the 1st quarter in 2009."

"The biggest variable impacting exam glove pricing is the decline in cost of the raw materials used to manufacture gloves," remarked Judson Boothe, marketing director of medical supplies, Kimberly-Clark Health Care. "The decrease in cost of raw materials has varied by glove material type, with the largest decreases seen in vinyl and latex gloves."

Tugging prices upward, however, said Tai, "medical glove production will feel the effects of stricter FDA standards that took effect December 19, 2008. The new FDA ruling tightens the acceptable quality levels (AQL) from the previous 2.5 for surgical grade gloves and 4.0 for examination grade gloves to 1.5 and 2.5 respectively. This measure harmonizes AQL's for pinholes and defects with consensus standards developed by International Organization for Standardization (ISO) and ASTM International. The tightening of FDA standards has made manufacturers implement more stringent quality control and has increased manufacture costs and decreased the supply of disposable gloves. Prior to the FDA changing their standards, Tronex's full line of exam gloves had already met the AQL level of 1.5," Tai noted.

"Glove manufacturers and distributors risk their products not being admitted into the U.S. marketplace or not considered appropriate for healthcare use if their gloves cannot meet these higher quality levels now required by the FDA," said Boothe. "Kimberly-Clark gloves are currently at AQL levels far exceeding industry norms. Our exam gloves are produced at a higher standard than specified by FDA."

Also affecting glove supplies and pricing, in July 2008, Hong Ray, the world's largest manufacturer of vinyl exam gloves, declared force majeure conditions saying it was unable to meet its normal customer agreements. Among the many factors cited as leading to production shortfalls, shipping delays and price increases, were a fire at a major raw material manufacturer; changes in Chinese government policy impacting labor, taxes and credit; the Beijing Olympics; the price of petrol; the weak U.S. dollar; energy inflation; paper cost increases; and the FDA AQL change from 4.0 to 2.5.

Several major glove manufacturers assured buyers of the stability of their glove supply levels. For example, noted Boothe, "by maintaining direct control over manufacturing for more than 95 percent of our exam gloves through the two Kimberly-Clark-owned facilities in Thailand, we have been able to increase and sustain production with very little interruption. In October 2007 we expanded our manufacturing capacity of the STERLING Nitrile exam glove to help meet rising global demand. These investments allowed Kimberly-Clark Nitrile exam glove customers to see no disruption in their nitrile exam glove supply during the market disruptions that occurred in the summer of 2008 from glove companies that sourced their nitrile exam gloves from external suppliers."

**"**Tronex is an Asian American owned company with a product category that is made in Asia. The cultural background, extensive knowledge and experience in international logistics and strong factory partnerships have allowed for total control, and for Tronex to keep increases to a minimum, we continue to look for operation efficiency," said Tai. "Our Company prides itself with an order fulfillment rate in excess of 99 percent. Tronex has a proven inventory planning system (2½ months of a buffer stock) that ensures consistent supply. When many suppliers were having trouble meeting demand, Tronex has been able to maintain a fulfillment rate of 99 percent for existing customers, while expending our business with good control. All Tronex factory partners have been with us for more than a decade. We ensure that we understand our customers' expectations and plan carefully with proper execution."

And according to Dr. Esah Yip, director of the Malaysian Rubber Export Promotion Council, "There is no shortage in supply levels with regards to natural rubber latex gloves. As a matter of fact, the glove industry in Malaysia, the largest exporter of rubber gloves in the world, has been growing strongly in recent years. Malaysia accounts for about 60 percent of the world demand of rubber gloves."

She added, "natural rubber latex gloves are known for their superior barrier properties and cost effectiveness. As such, they have been and still are widely used particularly in healthcare settings where effective barrier protection is of great importance against viral transmission and infectious diseases. With the exception of vinyl or PVC gloves, which have been shown to provide lesser barrier protection than natural rubber latex gloves, natural rubber latex gloves are generally less expensive

than many synthetic alternatives, such as polyisoprene, polychloroprene, polyurethane, co-polymer and often nitrile."

Alecia Cooper, R.N., M.B.A., C.N.O.R., senior vice president of clinical services marketing for Medline Industries, observed that "although there has been quite a bit of downward trending recently, there is still a lot of uncertainty with the future of exam glove prices and supply levels."

Medline's approach, noted Cooper, "to help keep cost increases to a minimum and to ensure adequate supply of gloves for our customers, we have decreased the size of our exam glove boxes. This has allowed us to be able to increase the amount of gloves sent with each shipment. It has also resulted in a decrease in packaging materials which has led to a reduction in waste. We have also worked to engineer some of our gloves so we can fit more in a box. Our new SensiCare Ice and Aloe*touch* Ice gloves come 200/bx (2,000/cs) versus the standard 100/bx (1,000/cs)."

Kimberly-Clark also encourages facilities to look at smarter packaging options. "One of the simplest ways to reduce glove costs is by evaluating the current levels of space and waste that a facility's exam gloves are currently taking up," said Boothe.

"Kimberly-Clark's Sterling Nitrile exam gloves offer the added benefit of freeing up precious storage space for critical items, and reducing waste through innovative packaging technology," offered Boothe. "For example, a facility that uses 6,000 cases of standard exam gloves can save up to 33 percent space by switching to Sterling Nitrile exam gloves. This is due to the package configuration, which provides 1,500 gloves per case over the 1,000 gloves that standard packaging provides. That means the same safety stock of gloves can be kept, while freeing up valuable storage space for other critical healthcare items. If you also take into account the rising costs of disposal, $0.11 to $0.45 per pound, the financial and environmental savings really add up. Several of our larger Sterling customers who were previously using latex exam gloves are now preventing 100 tons of waste disposal each year just by converting to our product. This yields potential savings of $22,000 to $90,000 annually."

Indeed, nitrile is becoming increasingly more popular as a non-latex alternative for exam gloves.

"A high quality nitrile exam glove is comparable in protection to a high quality latex glove," said Boothe. "Additionally, nitrile is highly chemical resistant, thus enhancing the level of protection to the healthcare worker. Further, standardizing on nitrile gloves eliminates confusion and the risk of accidental latex glove use in situations where the patient or treating professional is latex– sensitive."

"Clinical studies show that vinyl exam gloves fail in use more than one-third of the time," added Boothe. "They have limited elasticity, tensile strength and durability. They're not suitable for use with many chemicals, cause hand fatigue and are perceived as hot and less than optimal tactile sensitivity."

"[Nitrile gloves] are recommended for applications where gloves are worn for a

longer period of time or exposed to greater stress," said Medline's Cooper. "Nitrile gloves also have chemical barrier properties that give them an advantage when handling certain drugs or chemicals."

However, today's next generation vinyl gloves may provide an affordable alternative under certain conditions. "Traditional vinyl gloves have a tensile strength of about 11 MPa and are adequate for most routine nursing procedures. Newer second- and third-generation vinyl gloves are softer and stronger, with a tensile strength of 13-15 MPa. These gloves are an excellent general-purpose option," said Cooper. "All Medline gloves pass Viral Penetration Tests (ASTM1671D), although gloves only maintain effective barrier protection as long as they are intact. To help hospitals reduce glove costs, we have suggested that some facilities use vinyl exam gloves as opposed to latex or nitrile."

Dr. Yip cited the advantages of using low-protein gloves certified by the SMG quality program. "Natural rubber latex gloves, particularly low-protein SMG-certified gloves, especially the powder-free variety, are a viable option for the healthcare industry today for the following reasons:

"The awareness of latex protein allergy affecting certain sensitive individuals has been a concern among glove users. The cause of this allergy has been shown to be due to the use of an older generation of latex gloves with high residual protein content and excessive powder. Such concern can now be alleviated through the use of low-protein latex gloves resulting in vast reduction in incidences of sensitization and allergic reactions in work places, as shown by many independent hospital studies done in the U.S., Europe and Canada. More importantly, many latex allergic individuals wearing non-latex gloves, can now work alongside their co-workers using the low-protein gloves and suffer no ill effects."

Explained Dr. Yip, "to ensure users the latex gloves used are of low-protein, the SMG quality program certifies latex gloves that meet controlled low-protein limits. While all SMG-certified powdered latex gloves meet residual protein content requirement of not more than 200 microgram /square decimeter, as in line with that recommended by the American Society for Testing and Materials (ASTM) for both powdered and powder-free latex medical gloves, the upper protein level for powder-free SMG-certified gloves is however, not allowed to exceed 50 microgram/square decimeter."

Importantly in the current economic climate, noted Dr. Yip, "glove intervention involving the use of low-protein latex gloves as well as non-latex gloves for allergic individuals has been reported by various hospitals to have cost benefits, for example, Mayo Clinic reported a savings of about $200,000 annually."[1]

Tronex's Tai offered this advice for hospitals struggling to contain costs: "The cost of gloves has to do with consistent quality and supply. During a time of uncertainty, we feel that hospitals should only partner with reliable suppliers. Certain costs, such as material and transportation costs are beyond the control of suppliers and hospitals. However, a flexible contract agreement with a supplier of integrity would ensure that hospitals always have the fairest value pricing based on market conditions."

According to Milt Hinsch, technical services director, Mölnlycke Health Care, "there is

an easy, practical way to reduce costs by using gloves more sensibly in the OR. Latex gloves are often used when opening/setting up operating rooms. Then, because of the potential latex allergen contamination, if a latex-allergic patient should arrive for that room, the room must be torn down and re-set, at great cost to the facility. A few customers have told us that to avoid that huge, unnecessary expense, they always wear latex-free gloves (nitrile, chloroprene, PI) when setting up their operating rooms. The cost savings of avoiding just one re-set can easily offset the cost of using more expensive latex-free gloves for setups.

"In addition, hospitals can reduce glove costs by using group purchasing agreements, if available, and then increasing the usage of the contract glove brands to obtain the best tier pricing," Hinsch continued. "If a facility uses only 10 percent of the contracted glove brands, it can usually reduce that glove pricing by using a higher percentage of the contract gloves - let's say 80 percent to 90 percent of the total facility surgical glove usage.

"Finally, using the lowest acceptance quality limit (AQL) gloves saves customers money by providing surgical gloves with the lowest AQL for freedom from holes," he added. "That means that fewer holes are allowed in the gloves, so that the number of gloves discarded right out of the box because of manufacturing holes is likely reduced."

**Alternative latex**

While synthetic options are becoming more popular, latex is still considered the "gold standard" in medical glove material. "Natural rubber latex gloves are acknowledged to provide excellent barrier protection, in addition to superior properties like durability, unmatched comfort, fit, great tactile sensitivity, and high resistance to puncture and tear – qualities that many synthetic alternatives are attempting to achieve," explained Dr. Yip.

A few innovative companies are developing natural rubber latex (NRL) options with minimal levels of allergen-causing proteins.

Atlanta-based Vystar Corporation has developed Vytex NRL, a natural rubber latex in which the antigenic proteins are deactivated without affecting the desirable properties of latex. Alatech Healthcare has filed an FDA 510(k) for an exam glove made with Vytex NRL, as well as one for a condom. "To date, well over 500 protein test have been performed on Vytex and various products made with Vytex," said Bill Doyle, president and CEO of Vystar Corp. "While the protein level in latex can vary from tree to tree and season to season, we carefully monitor the protein levels, especially antigenic protein levels of Vytex NRL to ensure that users are exposed to significantly reduced levels of proteins in Vytex NRL and products made with Vytex NRL."

Added Doyle, "Vystar recently presented to the American Society for Testing and Materials' Natural Rubber Subcommittee (ASTM D11.22 ) and will be working with the committee to establish a new category of ultralow *Hevea* protein natural rubber latex that describes the attributes of Vytex NRL under ASTM guidelines."

There are also cost advantages to Vytex NRL. "Using Vytex NRL in place of traditional *Hevea* natural rubber latex or current glove synthetics in surgical or exam gloves is a cost effective proposition for both the manufacturer and the user/purchaser," said Doyle. "Gloves produced with Vytex NRL maintain or improve upon the desirable benefits of natural rubber latex; tensile strength, durability, barrier protection and comfort, fit and feel while significantly reducing the levels of antigenic proteins at a cost similar to nitrile in exams and considerable savings over the more pricier latex alternatives used in surgical gloves (neoprene and polyisoprene)."

An alternate type of NRL, harvested from desert shrubs grown in Arizona is Yulex guayule latex. In April 2008, the FDA cleared for marketing the Yulex Patient Examination Glove. While not yet produced commercially, "Yulex is working with glove manufacturers, which we hope will release a commercially-available glove in the near future," said Katrina Cornish, senior vice president of research & development at Yulex Corp.

"Yulex rubber is safe for people with life-threatening Type I latex allergies. Its tensile strength, elasticity, durability, protection and comfort are superior to synthetic products as well," said Cornish. "And unlike synthetic products, Yulex material is also renewable and an excellent way for hospitals to reduce their carbon footprints by avoiding petroleum-derived products or products imported from overseas. The process used to make Yulex latex are non-polluting and sustainable which also creates new sustainable, clean technology jobs in the U.S."

Besides the Yulex patient exam glove, the company "is working with surgical glove manufacturers to produce a guayule surgical glove, but this product is not likely to become available commercially in 2009," said Cornish. "We haven't found any medical products which use latex or synthetic polymers, that we cannot make from guayule, and a wide variety of medical products are in development with manufacturers." HPN

References:

1. www.latexglove.info – Health Safety

2. "Vytex Natural Rubber Latex: An Innovative Source Material for Natural Rubber Latex" http://www.vytex.com/pdf/ILC_2008_Vytex_NRL_Technical_Paper.pdf

---

**Gloves Spotlight**

**Gloves Vendor Chart**

**Healthcare Purchasing News**
**KSR Publishing, Inc.**