Cleanroom gloves or medical gloves?

Derek Watts

Suppliers of specialist gloves are often asked to supply medical gloves for use in cleanroom applications. On the face of it, this doesn't seem unreasonable, however the introduction of medical gloves into a cleanroom could have serious repercussions. A quick conversation is usually enough to help the customer to specify an appropriate product, but why does the misunderstanding arise in the first place? The following article sets out to explain why the two applications are often incompatible.

Perceived wisdom is that gloves used in medical environments are sterile, as the purpose of medical gloves is to prevent cross-infection from the clinician or surgeon to the patient. Surely, therefore, medical gloves MUST be very clean. This is a misconception and only partly true. The ultimate purpose of sterilising surgical gloves to be used in operating theatres is to prevent infection from bacteria which would otherwise be present on the gloves. Contrary to the belief of many, the standard dispenser boxed examination gloves used in medical and dental environments are NOT sterile, and all they can do is prevent cross infection spreading from the wearer of the gloves to the patient. The patient is NOT protected from the multiple bacteria that are already present on the gloves.

Dentists are still allowed to use powdered gloves but all medical gloves used in hospitals in the UK have to be powderfree. The traditional way to make a glove powderfree was for it to be put through a process of chlorination after it had been removed from the production line. The process of chlorination not only removed all the powder but it also killed the bacteria on the glove. As such, provided the packers of the exam gloves wore clean gloves, one could be reasonably assured that the examination gloves would have a very low bacteria count.

Nowadays, however, powderfree medical gloves are rarely made through a process of chlorination (inside and out), as in the interests of economy, other manufacturing methods for these gloves have been developed and established. Most powderfree medical examination gloves are now either produced on-line by dipping them into a polymer coating or by chlorinating them on-line prior to stripping them off the glove formers. Because gloves are moulded inside out, chlorination takes place ONLY on what is ultimately the inside of the glove. The outside does not come into contact with the chlorine and therefore the gloves will be prone to having a lot more bacteria as compared with off-line chlorinated gloves.

Pharmaceutical manufacturers will normally require sterile gloves, but in addition to the sterility, they also require the gloves to be low in particulates, especially if they are making injectables. There are many ways that particles get on the gloves. The main origin of the particles is human cells, followed by tiny fibres from clothing. There is little emphasis during the production and packing of surgical gloves on the minimisation of either of these, and as a result sterile surgical gloves frequently have high particle counts, albeit of sterile particles.

As a further indication of the lack of concern for particles in medical environments, you just have to look at the packaging of standard surgical gloves (see **Figure 1**). They are packed in paper inner wallets which are then, traditionally, sealed into paper pouches that have a tendency to shed particles when peeled open. The sealed pouches are then further packed into cardboard boxes. Paper is a no-no in all non-medical cleanroom environments, so all of this packaging is unacceptable. In contrast to the paper packing of surgical gloves, sterile cleanroom gloves are packed using non-particulating materials such as polyethylene inner wrappers and easy-tear pouches (**Figure 2**). All this packaging is itself manufactured in a cleanroom to ensure its cleanliness, and comes technically specified.

In some cases, it will not be necessary for pharmaceutical manufacturers to use sterile gloves, for instance if making tablets. However it is still important that the particulates on the gloves are low. Not only do the particulates need to be low, but the bacteria count on the non-sterile gloves will also need to be very low. This is why it is important that cleanroom gloves are used for

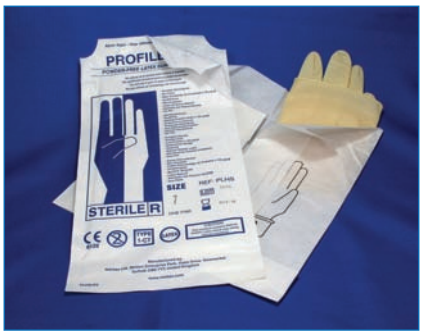


***Figure 1**: Surgical glove packaging showing peel pouch and paper wallet*

***Figure 2.** Cleanroom glove packaging showing easy tear pouch and PE wallet*

this application. All good cleanroom gloves are chlorinated off-line, meaning that both the inside and the outside of the gloves are thoroughly dosed in chlorine. They are then washed in highly filtered water to remove the residual chlorine and other particles.

Whilst the removal of particles is important for gloves used in the manufacturer of pharmaceutical products, removal of ionic contamination is not of importance. However, for the micro-electronics industry, whilst a low particle count is extremely important, in addition to this, many manufacturers also consider low ion counts to be a critical requirement. Ionic contamination can greatly reduce the yields in the manufacture of electronic products such as hard disk drives, printed circuit boards and silicon wafers. Ions such as chlorides, nitrates, sulphides, sodium, potassium, etc are by-products of the chemicals used in the manufacturing process. All of these particles rest on the surface of the glove and require mechanical removal. This is achieved by washing the gloves in ultra-pure, de-ionised water, and then drying just before packing.

Having demonstrated that medical gloves are not suitable for cleanroom use, we have to ask "what actually are the important characteristics of cleanroom gloves". The number one characteristic, which has already been established, is the cleanliness of both the glove and its packaging. However, beyond that, users have a wide selection of gloves to choose from to match their application. It is probably true to say that for every cleanroom application there will be a number of options available to the purchaser, and that final selection frequently comes down to the preference for one glove over another based on purely subjective criteria such as fit and feel, level of grip etc.

One thing that the user should be able to take for granted, is that the physical properties of the gloves should reach minimum standards. However, the cleanroom glove community has evolved without defining exactly what the minimum standards should be. This void has been partially filled by glove manufacturers using the existing medical glove EN 455 standards[1-3], to define dimensions, strength and limits on the numbers of pinholes as a basis for quality assurance and quality control in their factories. What is equally important is that glove manufacturers specify the cleanliness class for which the glove is suitable, as defined in EN ISO 14644-1[4], e.g. ISO Class 4 or ISO Class 5. It should be noted that some cleanroom gloves are also specifically chosen because they protect the wearer from harm from chemicals. These gloves are classed as Personal Protective Equipment (PPE) and are regulated under the European PPE Directive[5] and its associated standards[6]. Obviously such gloves must at the same time comply with cleanroom requirements.

The other issues that the specifier needs to consider are the shape of the gloves and the type of rubber used for their manufacture. Lower cost bulk packed non-sterile gloves are normally flat form, ambidextrous, with the thumb emerging at the side, allowing the glove to be donned on either hand. These gloves are excellent for general purpose use in the cleanroom, but every movement of the fingers and thumbs has to overcome the resistance of the glove material, which has a natural tendency to maintain its original shape. In most applications, this will not present a problem, however if the wearer is constantly engaged in very fine work, requiring precise movements, then the resistance of the glove can cause fatigue in the hand and, in particular, the finger muscles. For precision work, hand specific gloves are a much better option. Hand specific gloves are moulded with a slight curve to the fingers, and with the thumb offset to the front in a much more natural position than ambidextrous gloves. These design features mean that the wearer is not fighting against the natural behaviour of the rubber and instead the rubber is assisting the wearer where fine control is

Table 1. Relative performance of the four main glove materials

	Comfort	Elasticity	Strength	Durability	ESD performance
Latex	Excellent	Excellent	Excellent	Good, but punctures can be hard to spot	Very poor. Latex is an excellent insulator
Polychloroprene	Good; very close to Latex	Good	Good	Good	Poor – good insulator
Nitrile	Good; comfort improves with wearing	Medium	Medium	Good	Good. Static dissipative and improves with wearing
Vinyl	Fair; relatively stiff	Low	Low	Medium	Good. Static dissipative and improves with wearing

required. If operators are involved in very fine work, the thickness of the glove becomes important, as does the level of grip and the texture of the fingertips and palm.

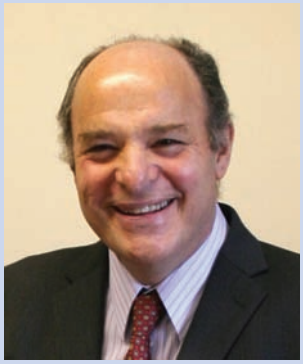
In terms of wearer comfort, natural rubber latex (NRL) is probably the best option because of its elasticity and strength. However, there are concerns surrounding latex allergies which can affect the wearer and also make the gloves unacceptable in some pharmaceutical manufacturing applications where possible contamination with NRL proteins would render the processed drugs unusable. The alternative synthetic rubber materials are Polychloroprene, Nitrile and Vinyl.

Amongst the synthetic rubbers, Polychloroprene has the characteristics closest to NRL and provides a very good alternative. Nitrile and Vinyl are stiffer materials with vinyl being the least elastic; however both nitrile and vinyl have good electrical conductivity properties making them ideal for use in electronics manufacturing or other static-sensitive environments such as explosive or combustible atmospheres.

In conclusion, it is simple to state that medical gloves should not be used in a cleanroom environment. Medical gloves may appear to be clean (and might even have been sterilised), but in cleanroom terms they can be very dirty. Cleanroom gloves are available in different materials, different shapes, different lengths, different thicknesses and different textures and levels of grip. It is, therefore, important that the person specifying the gloves knows a) what level of performance is required to match their process, and b) what the requirements of the wearers are. For some applications, the selection of the correct glove will be straightforward, but for others a bit more work may be required. Any good manufacturer of cleanroom gloves will be able to provide written specifications, advice and samples to aid the decision making process.

References

1. EN 455-1: 2000, Medical Gloves for single use – Part 1: requirements and testing for freedom from holes.
2. EN 455-2: 2009, Medical Gloves for single use – Part 2: requirements and testing for physical properties
3. EN 455-3: 2006, Medical Gloves for single use – Part 3: requirements and testing for biological evaluation.
4. EN ISO 14644-1:1999, Cleanrooms and associated controlled environments, Classification of air cleanliness
5. 89/686/EEC, Council Directive on the approximation of the laws of the Member States relating to personal protective equipment
6. Gloves as PPE: Standards for permeation and penetration, Derek Watts, Clean Air and Containment Review, Issue 2, April 2010



Derek Watts worked on the original Channel Tunnel project, having graduated in 1974 with a BSc in Mining Engineering from Imperial College. In 1975 Derek joined Philip Brothers (Phibro), the commodities trading division of Investment Bankers Salomon Brothers, which operated 42 offices worldwide. He remained with the company for nearly 15 years, working in London, New York and Bangkok before settling in Kuala Lumpur and becoming the company's youngest ever Managing Director. In late 1988, correctly forecasting the surge in demand for examination gloves, Derek constructed a gloves factory, quickly moving from standard powdered exam gloves to specialise in powder-free cleanroom gloves. He pioneered many innovations under the Bioclean brand, including the introduction of no-paper packaging of sterile cleanroom gloves for the pharmaceutical industry. Having grown glove sales to over 100 million gloves per annum, Derek sold the business and moved back to the UK in 1996 where he incorporated Nitritex Ltd to import and distribute the BioClean gloves. Under his leadership, the company became profitable within 12 months and has, since then, greatly expanded its product range, opened subsidiaries in four countries to service a global client base and achieved consistent double-digit annual growth.

Correspondence to: Derek Watts, NITRITEX, Minton Enterprise Park, Oaks Drive, Newmarket, Suffolk CB8 7YY, UK. Tel: +44 (0) 1638 663338; Fax: +44 (0) 1638 668890 derek@nitritex.com; www.nitritex.com