Brosch

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Glove Guide

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Glove Types

Examination gloves are usually made from Latex, Vinyl, Nitrile or a hybrid. The different costs per glove type are primarily due to the difference in raw material costs.

Latex (Natural Rubber Latex)

Natural Rubber has been used to make medical gloves for over a century. The material comes from the Hevea Brasiliensis tree which is grown in sustainable plantations in south-east Asia. After processing the natural rubber creates a glove that is white to amber in colour and possesses a high degree of strength and elasticity.

Nitrile

The nitrile rubber used to manufacture standard nitrile gloves is generally stiffer that that used for accelerator free nitrile gloves. It is manufactured from petroleum feedstock and as such contains none of the proteins that may cause allergic reactions to natural latex rubber.

Accelerator Free Nitrile

The nitrile rubber used to manufacture these products is specially formulated to provide a softer material that provides increased elasticity and an improved feel. The process does not use accelerators to speed up the formation of the glove and so, the glove tends to be more expensive than standard nitrile.

Vinyl

Vinyl is a plasticised (softened) plastic manufactured from petroleum feedstock. Feedstock are vinyl chloride monomer (VCM) or spot ethylene dichloride (EDC). VCM is used to make polyvinyl chloride (PVC) which is used to manufacture vinyl gloves. Vinyl gloves do not contain any proteins or accelerator chemicals associated with latex and nitrile gloves.

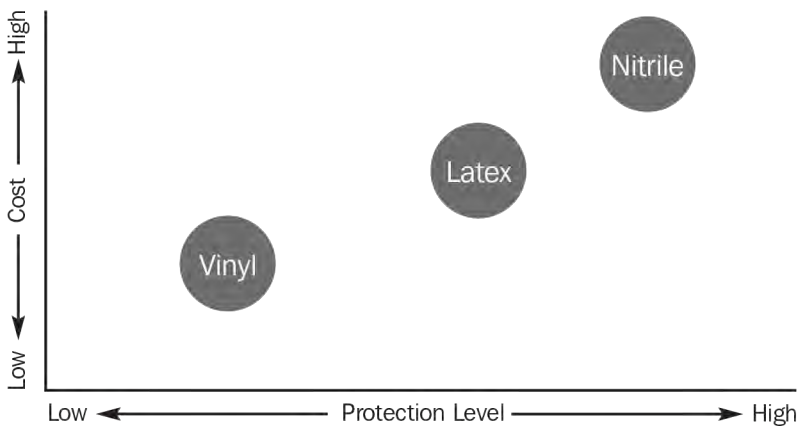
Vi-ni (A blend of Vinyl and Nitrile)

The blend consists of 80% Polyvinyl Chloride and 20% Nitrile Butadiene. It was produced to provide a glove with similar properties to vinyl but with a tighter fit and slightly higher force at break.

Benefits of the Different Glove Materials

Exam gloves can be manufactured in numerous colours, but the colour does not determine the material composition or safety level

Cost vs Protection Level of Exam Gloves



Strength/Thickness

The most important glove property will be the thickness and formulation of the glove. The thickness of a glove does have a bearing on the tensile strength but just because a glove is thick it doesn't mean the glove will provide adequate protection.

Features & Benefits of Glove Types

Latex (Natural Rubber Latex)

- Strength - Natural rubber latex has a high tensile strength that is highly durable.
- Fit – the elasticity of the material means that it 'clings' to the hand providing an excellent tactile sensitivity (feel).

Nitrile

- Strength – the nitrile rubber generally has a higher tensile strength than natural rubber.
- Fit – not as elastic as natural rubber latex but will conform to the hand within a short period of time.
- Chemical resistance – nitrile rubber is resistant to a range of chemicals including cytotoxic drugs.

Accelerator Free Nitrile

- Accelerator free – the glove does not contain accelerator chemicals reducing the risk of skin sensitivity and type IV allergy.
- Strength – the strength is comparable to natural rubber latex.
- Fit – not as elastic as natural rubber latex but will conform to the hand within a short period of time.
- Chemical resistance – nitrile rubber is resistant to a range of chemicals including cytotoxic drugs.

Vinyl

- Strength – vinyl gloves have a lower tensile strength compared to latex and nitrile, they still comply with EN455.
- Fit – vinyl is stiffer than natural latex and nitrile rubber, and undergoes less distortion but the fit is not as snug as latex and nitrile gloves.
- Rare skin irritation.

Vi-ni (A blend of Vinyl and Nitrile)

- Strength – typically the gloves have a slighter higher strength than vinyl but are not as strong as natural latex and nitrile rubber.
- Fit – the fit is tighter than vinyl but not as snug as latex and nitrile gloves.
- Negligible skin irritation.

Glove Classification

Medical examination gloves are classified as medical devices and are classified depending on there use and are risk based:

Classification	Level of Risk	Example of classification requirements
Class I	Low	All non- invasive and invasive devices for use with body orifices for transient use.
Class Ia	Low - Medium	All sterile non-invasive devices
Class IIa	Low - Medium	All surgically invasive devices that are intended for transient use or short term use.

Class I devices – conformity assessment can be carried out by the manufacturer, who once satisfied can create a declaration of conformity.

All other classes (Is, Im, IIa, IIb, III) require the intervention of a notified body, whereby the quality systems and product conformity must be assessed by the notified and an EC certificate of conformity issued to confirm approval.

Medical examination gloves	Class I
Sterile medical examination gloves	Class Is
Procedure packs / Dressing Aids	Class Is
Surgical Gloves	Class IIa

Glove Classification...

Under the medical devices directive, the medical examination gloves are tested to and comply with the following harmonised British / European Standards:

BS EN 455-1 Medical gloves for single use: Requirements and testing for freedom from holes
BS EN 455-2 Medical gloves for single use: Requirements and testing for physical properties
BS EN 455-3 Medical gloves for single use: Requirements and testing for biological evaluation
BS EN 455-4 Medical gloves for single use: Requirements and testing for shelf life determination

BS EN 455-1

This standard describes a method in which randomly sampled gloves are subjected to a water-tightness test (ability to hold 1000ml of water without leaking). The number of gloves to be tested is based on the batch size of the gloves manufactured as stated in the International Standard ISO 2859-1. For compliance to the BS EN 455-1, the accepted quality level shall be 1.5%.

BS EN 455-2

This standard describes the testing requirements for determination of physical properties, including sizing, break strength, before and after accelerated ageing, of medical gloves for single use, surgical gloves, examination/procedure gloves, long-cuff medical gloves.

Dimensions - Examination Gloves:

Size	Length – mm (median value) Tip of middle finger to bottom of cuff	Palm Width – mm (median value)
XS	≥ 240	≤ 80
S	≥ 240	80 ± 10
M	≥ 240	95 ± 10
L	≥ 240	110 ± 10
XL	≥ 240	≥ 110

Dimensions - Surgical Gloves:

Size	Length – mm (median value) Tip of middle finger to bottom of cuff	Palm Width – mm (median value)
5.0	≥ 250	67 ± 4
5.5	≥ 250	72 ± 4
6.0	≥ 260	77 ± 5
6.5	≥ 260	83 ± 5
7.0	≥ 270	89 ± 5
7.5	≥ 270	95 ± 5
8.0	≥ 270	102 ± 6
8.5	≥ 280	108 ± 6
9.0	≥ 280	114 ± 6

Force at Break - Strength

Glove Family	Description of Material	Force at Break - N
Surgical Gloves	Requirements for gloves made from natural rubber latex	≥ 9.0
	Requirements for gloves made from all other elastomer materials (polycholoroprene, synthetic polyisoprene, nitrile, styrene block copolymer, polyurethane)	≥ 9.0
Examination Gloves	Gloves made from elastomeric material other than nitrile (natural rubber latex, polychloroprene, synthetic isoprene, styrene block copolymer, polyurethane)	≥ 6.0
	Gloves made from nitrile.	≥ 6.0
	Gloves made from thermoplastic materials (polyvinyl chloride, polyethylene)	≥ 3.6

Glove Classification...

Latex (Natural Rubber Latex)

Latex gloves have been a traditional choice for the healthcare industry. However, concerns regarding latex allergies have resulted in some organistations introducing latex free policies. Latex gloves are unsurpassed when it comes to durability, tactile sensitivity, comfort and fit.

The benefits are high tensile strength, good fit providing an excellent fee/touch with low instances of hand fatigue. The risks are allergic reactions to the natural latex proteins and low level risk to accelerators used in the manufacturing process.

Nitrile

The use of nitrile gloves has risen over the years to become the alternative to latex gloves. Nitrile gloves provide excellent protection to a wide range of chemicals as well as being an effective barrier against blood-borne pathogens.

Nitrile gloves are more puncture resistant, less likely to tear than latex gloves. Nitrile gloves are usually manufactured in two thicknesses to achieve either a 6 newton force at break or a higher 9 newton force at break.

The downside of nitrile gloves is that the fit is not as good as a latex gloves and users can develop allergies to the accelerators use in the manufacturing process. Hence, Accelerator free nitille gloves are available.

Vinyl Gloves

Vinyl gloves are manufactured from Polyvinyl Chloride (PVC). Healthcare facilities have be using vinyl gloves as a synthetic alternative. Vinyl gloves are the most economical glove type for cost conscious facilities. The gloves comply with BS EN 455 but have a lower tensile strength when compared to latex and nitrile. Vinyl gloves only have to achieve a force at break of 3.6 newons.

The fit of a vinyl glove is not as snug as a latex or nitrile glove, but there are very few cases of skin irritation. Vinyl gloves should only be used to carry out low risk procedures and should not be used in high risk or hazardous conditions.

Vinyl gloves have weaker chemical and viral protection levels than latex and nitrile, however they do provide a standard barrier protection. Vinyl gloves are cheaper in comparison to latex or nitrile and often the price will vary. It is important to ensure the correct quality of vinyl glove is used.

Vi-ni (A blend of Vinyl and Nitrile)

Vi-ni gloves are a blend of vinyl and nitrile compounds. The blended glove has a higher force at break than vinyl, typically 4 newtons, plus the fit is slightly better than vinyl. The gloves still have a loose fit and therefore can be affected by chemicals.

Sterile Exam Gloves

A range of latex, nitrile and vinyl glove are available that have been sterilised. Sterile gloves are used when caring for patients with open wounds to prevent infection.

Surgical Gloves

Surgical gloves are high quality sterile gloves manufactured in both latex and synthetic variants. Surgical gloves are usually hand specific and are of a higher grade of glove. These gloves have to achieve a force at break of 9 newtons and are classed as a Class IIa medical device. Surgical gloves also have a longer cuff length for enhanced barrier protection and to prevent cross contamination.

Medical Glove Usage / Risk Assessment

Background
The law requires that employers perform a risk assessment to identify any hazards faced by their employees and other individuals that they are responsible for (such as patients). This risk assessment process should weigh the benefits and risks of using a product in the light of current recommendations and regulations and come to a justifiable conclusion regarding its use. This process is complicated if the employer does not know all of the relevant facts regarding the products that the employees are using. The aim of this usage guide is to provide those facts for the medical glove range.

Things to Consider
Each employer should identify those tasks for which gloves are needed and consider the requirements upon the gloves if they are to be successfully used. The Infection Protection Society (IPS) and Royal College of Nursing (RCN) suggests that the following factors are considered:

- The likelihood of exposure to blood, body fluids, secretions and excretions.
- The potential for contact with non-intact skin and mucous membranes.
- The length of the procedure.
- Whether or not a sterile or non-sterile glove is required.
- Patient/user sensitisation to natural rubber latex or other materials.
- Potential contact with any chemicals, drugs or other substances.
- The need for dexterity and tactility.

Recommendations and Requirements for Medical Gloves
These requirements apply to medical gloves. Gloves used for industrial purposes, such as for domestic work, will be subject to a different set of standards and requirements.

Gloves should:
- Carry the CE mark.
- Conform to the EN455 series of standards.
- Be powder-free and contain less than 50µg/g natural rubber latex proteins.
- Contain a low level of residual accelerator.
- Comply with EN556 if they are sterile.
- Comply with ISO11135 if they have been sterilised by ethylene oxide gas.
- Comply with ISO11137 if they have been sterilised by gamma irradiation.

Vinyl Gloves and Bacterial / Viral Protection:
Many questions are asked whether vinyl gloves can be used to handle blood. Vinyl gloves can be used for handling bedpans and urinals, as well as for contact with body fluids. They are generally used for low risk procedures but do provide protection against bacterial and viral penetration, providing the film barrier is not compromised.

Although the vinyl gloves have undergone viral penetration studies in accordance with the standard ASTM F1671-1 (using bacteriophage Phi- X174) and did not show any penetration of the virus; it is not recommended to use vinyl gloves as they have a lower force at break (strength) compared to nitrile gloves.